University of Dundee

DOCTOR OF PHILOSOPHY

Understanding effective communication in dental primary care the dentally anxious patient, an example of special care dentistry

Hally, Jennifer Duncan

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2011

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Understanding effective communication in dental primary care

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Jennifer Duncan Hally

2011

University of Dundee

UNDERSTANDING EFFECTIVE COMMUNICATION IN DENTAL PRIMARY CARE: THE DENTALLY ANXIOUS PATIENT, AN EXAMPLE OF SPECIAL CARE DENTISTRY

Thesis submitted in accordance with the requirements

of the University of Dundee

for the degree of

DOCTOR IN PHILOSOPHY

to the Faculty of Medicine, Dentistry and Nursing,

by

Jennifer Duncan Hally BDS., MDSc.

University of Dundee
April 2011

Soli Deo Gloria

Solo Christo

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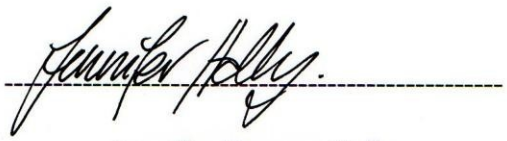
This project has been truly challenging and is indeed a labour of love.

DECLARATION

I declare that I am the author of this thesis and that I have consulted all the references cited. The work of which this thesis is a record has been done solely by me and it has not been previously accepted for a higher degree.

University of Dundee, 7th April 2011



Jennifer Duncan Hally

STATEMENTS

Statement 1

This thesis is being submitted in fulfilment for the requirements for the degree of Doctor of Philosophy.

Signed.....candidate

Date...7th April 2011

Statement 2

This is the result of my own independent work and investigation except where otherwise stated. Other sources are acknowledged by citing references. A bibliography is appended.

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Statement 3

I hereby give consent for my thesis, if accepted, to be available for photocopying and inter-library loan, and for the title and summary to be made available to outside organisms.

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CERTIFICATE

We hereby certify that Jennifer Duncan Hally has fulfilled the conditions of Ordinance 39 of the University of Dundee and is qualified to submit this thesis for the degree of Doctor of Philosophy.

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ABSTRACT

Understanding Effective Communication in Dental Primary Care: The Dentally Anxious Patient, an Example of Special Care Dentistry

JD Hally

BACKGROUND: More than 10% of UK adults suffer extreme dental anxiety. Effective verbal and non-verbal communication (VNVC) in the dental dyad following handover of a completed Modified Dental Anxiety Scale (MDAS) had been hypothesised to reduce dental state anxiety. This study aims to consider whether: (1) 'MDAS completion and handover effects long term dental trait anxiety, and (2) 'what VNVC elements influence patient anxiety reduction?'

TRIAL DESIGN: Mixed methods: (i) a randomised cross-over study and (ii) an observational study.

METHODS: Six NHS Highland Salaried Dental Practices were randomised to start either with the experimental arm, where dentally anxious patients (MDAS score ≥ 19 or 5 in any one question) complete and handover MDAS to the dentist, or the control arm where no handover occurred. Within the observational study, all participants had their dental treatment appointment videoed. The primary outcome was dental trait anxiety as measured by MDAS, pre-treatment and at 3 month follow-up.

Secondary outcome was dental state anxiety, measured pre and post treatment using both the Spielberger State-Trait Anxiety Inventory (STAI-S) and Heart rate.

The observational study analysed the first 2 minutes of video and related this data to the behavioural and affective outcomes.

RESULTS: 54 patients agreed to take part in the study with 47 completing 3 month follow-up. The randomised cross-over study found no difference in state or trait dental anxiety however observational outcomes showed dental state anxiety remained high when handover was blocked. A significant lack in decline in dental trait anxiety was shown when dentists blocked patient expressed cues and concerns; this occurred irrespective of patient gender, age or number of appointments received in a 3 month period ($F[155.06]=7.51$, $P=0.009$).

CONCLUSIONS: VNVC flow is fundamental to dyadic balance even within the first two minutes of the patient-dentist interaction. The balanced dyad is key to dental anxiety reduction.

Chapter 1

Introduction

1.0 Introduction

> *"Although the patient's dental condition is the main reason he or she seeks treatment, such overwhelming numbers of anxious patients strongly suggest that they may seek acknowledgement of their emotional needs as well."... "From a practice management perspective, using emotional communication has to be one of the least expensive, most effective practice-building tools available to dentists."* [1]

Effective verbal and non-verbal communication between dentists and their patients is thought to influence patient dental anxiety. Around 12% of the United Kingdom (UK) adult population claim extreme dental anxiety.[2] Yet despite improvements in dental techniques, pain control and an increased professional awareness to build good quality patient-dentist relationships, dental anxiety continues to play a significant role in the everyday patient-dentist interaction.[3, 4, 5, 6]

Over the last 50 years, the number of patients in the UK claiming dental anxiety has reduced.[7] Nevertheless, the latest Adult Dental Health Survey reports that just under half (48%) of UK adults who had ever been to the dentist, experience moderate to severe dental anxiety.[8] This makes dental anxiety perhaps the most common form of Special Care requirement in general dentistry today.[9]

Indeed according to the Medical and Dental Defence Union of Scotland (MDDUS) there is a real need to understand the special needs of anxious patients in general practice, particularly with reference to establishing informed consent prior to treatment and their potential as a future risk of dentist litigation.[10]

For patients, however, who experience dental anxiety, the impact particularly on the day of their appointment can be debilitating; resulting in either in an inability to comply with required treatment or for some who experience extreme symptoms, culminating in avoidance behaviour.[11, 12, 13] Such patients have been shown to be those with the poorest oral health-related quality of life in Britain.[14]

It is therefore important for the dental profession, to not only be able to provide ways to alleviate dental anxiety but also identify those patients who require help when they do manage to present for treatment. Indeed, according to current guideline development, there is a need to identify dentally anxious individuals, particularly in relation to establishing quality responsive care.[15]

Simple psychological inventories can be used as a means of identifying dentally anxious patients, yet despite the benefits of using such clinical tools, few dentists routinely use them. Indeed, a 2001 study by Dailey et al.,[16] highlighted low use of pre-treatment dental anxiety inventories even in a group of dentists expressing a special interest in the treatment of dentally anxious patients.

Interestingly, of those who did use an anxiety inventory, the index of choice was the Modified Dental Anxiety Scale (MDAS).

In a further study by Dailey et al.,[17] and a subsequent undertaking by Hull et al.,[18] this use of this simple MDAS form, was also seen to have a significant clinical effect on patient state dental anxiety when the form was handed directly from patient to dentist.

Both studies (randomised controlled trials) were set in Primary Dental Care and were therefore subject to the time constraints of the busy practice setting. The prospect of the use of such a clinically acceptable, simple intervention with the potential to influence patient dental anxiety is certainly worth further investigation.

Yet, the mechanism by which patient dental anxiety reduces, following MDAS handover has yet to be investigated, although the provision of a summary profile of anxiety to the patient's dentist may in itself be construed as a formal means of communication.

Indeed both Dailey et al.,[17] and Hull et al.,[18] claimed that the effect of MDAS may be due to the fact that it may have been used to facilitate patient-dentist communication; with Hull et al.,[18] clearly stating that dental anxiety did not decrease significantly unless patient-dentist 'discussion' regarding dental anxiety took place.

In other words, effective communication in relation to a patient's dental anxiety prompted by MDAS handover could be the key to patient dental anxiety reduction. Nevertheless the question remains, "what is effective communication?"

According to Berry, effective communication is simply the act of imparting "the right information, to the right people, in the right way, at the right time",[19] yet this definition almost overlooks the issue of quality.

Health communication experts agree that although communication is central to clinical function, it is the quality or 'effectiveness' of this interaction that is directly related to positive health outcomes.[20] Therefore, in this thesis 'effective communication' will be considered as a combination of both viewpoints, being defined as the ability to achieve a desired beneficial health outcome, responsive to an individual's particular needs.

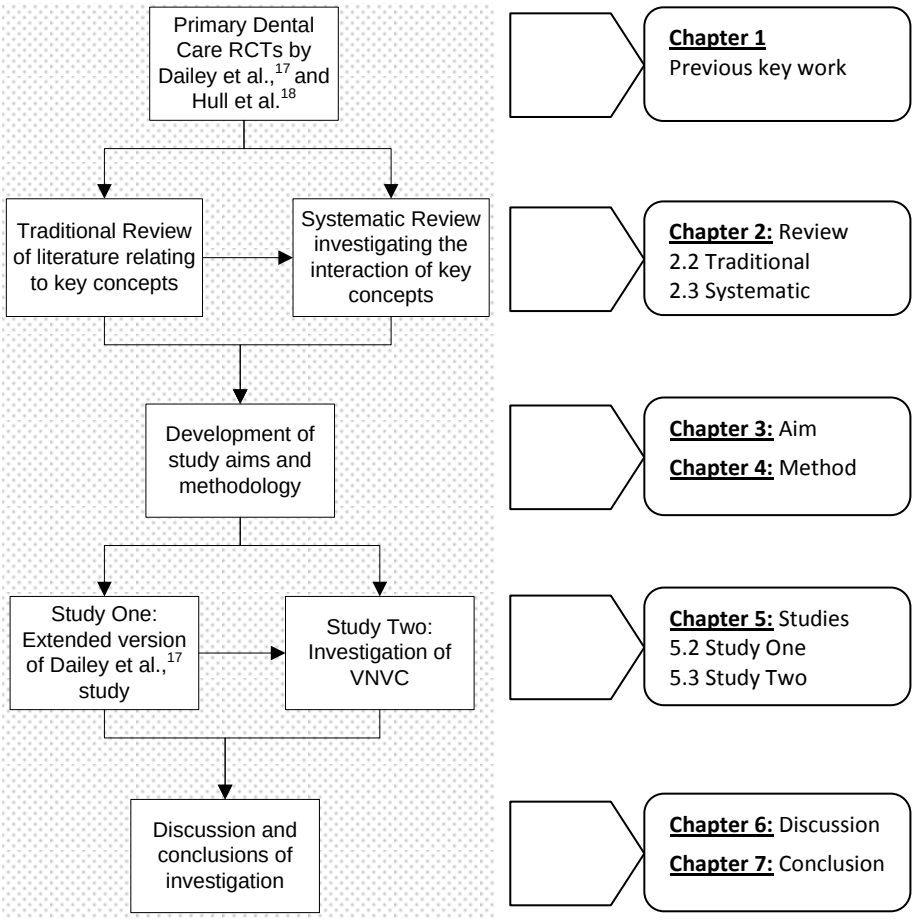
The dental profession is more than aware that there is a need for effective communication in the dental surgery setting[21, 22, 23] but no scientific evidence exists as to what elements of the patient-dentist interaction actually make a difference?

Of the limited work that has been undertaken to investigate the patient-dentist dyad, all have been set in Secondary Dental Care and none have considered the effective elements of communication on dental anxiety as a health outcome.[24, 25, 26] Despite the current weakness in the evidence base, numerous studies over the years have emphasised the need to analyse the actual verbal and non-verbal elements that make up the effective components of the patient-dentist interaction.[27, 28, 29]

The issue, however appears to be in the mechanism by which this can be done successfully within the Primary Care arena. This is the challenge that this thesis wishes to address by not only investigating the claims of both Dailey et al.,[17] and Hull et al.,[18] regarding the effect of MDAS handover on patient anxiety but also the associated verbal and non-verbal communication (VNVC) *actually* expressed during the Primary Care dental visit.

The author acknowledges the importance of the work undertaken by Dailey et al.,[17] and Hull et al.,[18] by using this as the platform for thesis development (see Figure 1).

Figure 1: Thesis Structure



Chapter 2 will investigate the current evidence base relating to the key themes expressed in both studies by using two review formats. Chapter 2.2 will employ a traditional narrative review, to consider the evidence base relevant to the main concepts of Health Communication and dental anxiety.

This will include the conceptual framework for dental anxiety reduction through effective communication, and a composite concept of 'balance' and relationship as alluded to by Burke and Freeman,[30] Rouse et al.,[1] and Roter et al.[31]

This will be followed by a rigorous systematic review investigating the link between 'face to face' communication in the healthcare setting with patient anxiety as a health outcome (Chapter 2.3).

From the results of these initial investigations a concise definition of study aims and objectives (Chapter 3) will be developed followed by a description of the chosen study methodology (Chapter 4).

The actual studies will be presented in Chapter 5 where two main approaches will be employed. Chapter 5.2 will use the structure of the Dailey et al.,[17] and Hull et al.,[18] studies to further consider the effects of MDAS handover (as a communicative element) on patient health outcome as measured by the Spielberger State Trait Anxiety Inventory (STAI-S), Heart Rate and MDAS change scores. The second (Chapter 5.3) will consider the actual behavioural and affective (emotional) elements of the dentist's verbal and nonverbal response to expressed patient dental anxiety.

Chapter 6 will discuss these findings in relation to the concept of 'balance' in the patient-dentist relationship, while Chapter 7 will close this thesis by drawing relevant conclusions from the investigation.

Chapter 2

Literature Review

Chapter contents:-

2.0 Literature Review

2.1 Review Introduction

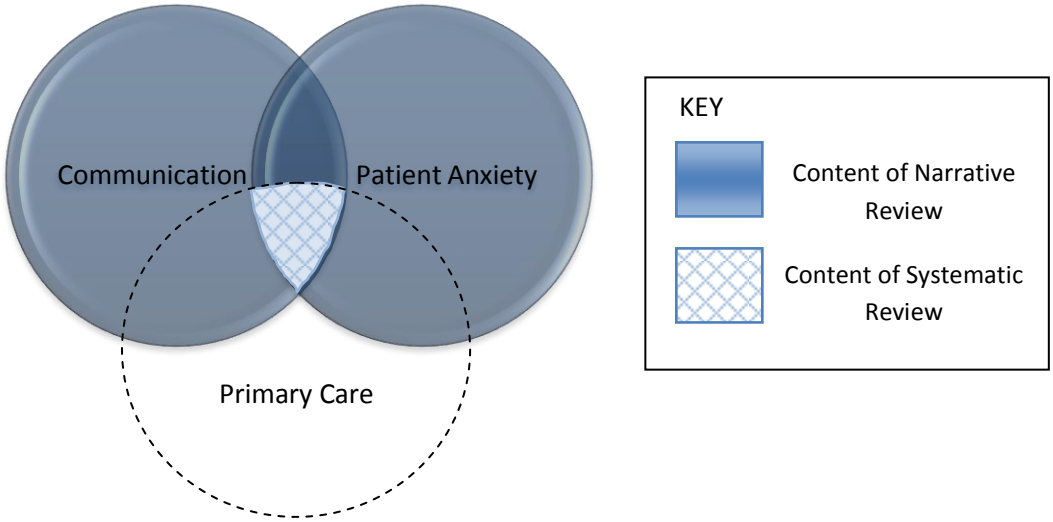
To understand the importance of effective communication and its hypothesised relationship with dental anxiety, it is essential to consider both the concepts and relationship within a wider evidence based framework. To do this, the body of literature relating to healthcare communication and patient anxiety will be collated and reviewed.

> *"A literature review is an objective, thorough summary and critical analysis of the relevant available research and non-research literature on the topic being studied"* [32]

The approach adopted by the author to consider both these concepts and their important relationship, so ensuring a comprehensive critique of the available literature, was to write two sections; a more traditional narrative review (Section 2.2) and a rigorous systematic review (Section 2.3). The conceptual structure of this review is highlighted in Figure 2.

Figure 2 illustrates the interplay of the key concepts in the context of both the narrative and systematic reviews.

Figure 2: Structure of Literature Review



The content of the narrative review (highlighted by the blue coloured areas), considers the evidence base of communication, patient anxiety and their relationship throughout all healthcare forums; Primary, Secondary and Tertiary.

The systematic review in contrast, focuses on the relationship between communication and patient anxiety within the Primary Care arena. This is highlighted by the 'hatched' blue area at the intersection of the circles in Figure 2.

By having this two-fold approach, the author aims to highlight the importance of contextualising scientific results to ultimately answer, not only the question of whether an intervention works but also to examine why.[33]

2.2 Narrative Review

2.2.1 Introduction

This narrative review provides a contextual setting for both the systematic review highlighted in Section 2.3 and the development of the primary research undertaken in this thesis.

According to Collins,[34] there is a real need to balance the strengths of systematic and narrative reviews and it is the author's aim to provide this by adopting such a twofold approach. The initial narrative review, as highlighted in this section, endeavours to establish a pathway through the depth of theories, models, and empirical evidence (examining both dental and general healthcare documentation) that make-up the diverse and complex fields of Health Communication and patient anxiety.

The literature collated and reviewed for both concepts stem from the systematic search of electronic databases documented in Section 2.3. While a rigorous inclusion and exclusion methodology was used in the systematic review, all documentation retrieved, relating to Health Communication and patient anxiety was considered for the traditional or narrative review so allowing a more comprehensive analysis of the available evidence base. The traditional review also employed the use of the snowballing technique[35] (using references cited in one document to lead to others), as well as literature published by field leaders, key texts and conference proceedings. It is the aim of this section to provide a platform for the discussion of effective face to face communication in the dental setting and its relationship with dental anxiety.

Health Communication

"Within the last few decades, the amount and quality of research in the field of Health Communication has increased substantially. One reason for this significant growth is the realization that communication itself is a core issue within medical [and dental] encounters." [36]

2.2.2 Communication: The Concept

Ἐν ἀρχῇ ἦν ὁ λόγος.....[37]

"In the beginning was the word...." [38]

Health Communication evolved from the concept of communication which finds its roots deep within antiquity. Both Aristotle[39] and Heraclitus[40] philosophised about the nature of communication using the Greek word 'λόγος' or 'logos' to encapsulate this collection of human thought and utterance as part of reasoned discourse. Yet despite the depth of meaning infused in ancient Greek rhetoric, the actual English word 'communicate' is derived from the more mechanistic Latin verb 'commincare' which simply means to share, divide out or to make common.[41]

Today, regardless of its simple etymological roots, the concept of communication is far more diverse in application and complex in its interdisciplinary underpinning than ever before.

In 21st Century society communication and communication technologies play an integral part in how humans interact with one another; information technology (television, radio and computer networks) has evolved at an exponential rate to support Mass Media, industry, healthcare and globalization.

> *"The debate regarding how much technology is too much continues at differing levels, but no one seriously argues against technology any more, even in the dental office. However, the discussion in dentistry is different from that in general industry. While society, in general, is becoming increasingly accustomed to direct or indirect contact with automation, dentists must be careful not to allow technology to interfere with the relationship between patient and doctor or patient and staff."* [42]

Indeed, the concept of communication does not belong to one particular area in society or academic discipline but finds itself straddling the divide between specialties as diverse as healthcare to journalism and theology to psychology.[43] Nonetheless, over the last seven decades many scholars have tried to define communication based on their particular field of expertise, yet the vastness of this concept has remained out with the boundaries set by their descriptions.[44] In other words, communication isn't just: "the verbal interchange of thought or idea";[45] or the "process that links discontinuous parts of the living world to one another",[46] but is instead a multifaceted, dynamic concept that changes through time being composed of many conceptual components.

Indeed, Frank Dance in 1970 examined different ways of conceptualising or defining communication resulting in 15 conceptual components and a conclusion that we're "trying to make the concept of communication do too much work for us."[47]

Yet it is this complexity that is intrinsic to the nature of not only human communication but also Health Communication; with scholars agreeing to disagree on any 'one size fits all' universal definition.

2.2.3 Defining Health Communication

According to Rogers, Health Communication relates to "any type of human communication whose content is concerned with health".[48] Despite the simplicity of this statement, Health Communication is a challenging concept to define. It is inevitable that as an applied subgroup of the Communication discipline, it reflects the complexity and theoretical underpinning of its root concept (Appendix 1) however in addition, Health Communication also encompasses the concept of health; equally as challenging to define and still hotly debated.[49,50] In an attempt to overcome this challenge, Health Communication scholars like Schiavo, often adopt a more pragmatic stance.

> *"[Health Communication is] a multifaceted and multidisciplinary approach to reach different audiences and share health related information with the goal of influencing, engaging, and supporting individuals, communities, health professionals, special groups, policy makers, and the public to champion, introduce, adopt or sustain a behaviour, practice, or policy that will ultimately improve health outcomes."* [51]

Despite this pragmatic viewpoint however, the essence of Health Communication is still a combination of two very diverse and complex domains; that of health and communication.[52]

2.2.4 Distinctive Tensions in Health Communication

It is perhaps the result of the combination of such weighty concepts (health and communication) that create the discipline's distinctive intrinsic tensions. These characteristic tensions as discussed by Babrow et al.,[53] make Health Communication significant from the main body of communication literature. These tensions can be summarised under four main headings.

- The tension between science and humanism;
- The tension between idiosyncrasy and commonality;
- The tension between certainty and uncertainty;
- And the interplay of the body and communication.

According to Babrow et al.,[53] Health Communication often finds itself uncomfortably bridging the gap between: today's scientific advances promoting longevity of life and one's actual human frailty;[54] the idiosyncratic view of holistic individual care and disease as a distinct entity to be treated on a population basis; [55, 56] and the level of certainty and uncertainty in relation to any patient's disease, treatment and recovery.[57, 58] Perhaps however, the most interesting tension is that of the interplay of the body and communication.

2.2.5 The Human Body and Communication

According to Babrow et al.,[53] there appears to be an intimate yet complex relationship between the body and communication. Indeed human communication, both verbal (the use of words) and non-verbal (body language and paralanguage), is dependent on this connection.[59] Indeed, the profound nature of this link means that consciously or unconsciously, individuals provide information about themselves to the outside world, supporting Watzalawick et als., conclusion that "one cannot not communicate".[60]

In Health Communication however, it is the tension between such closely connected elements that is significant. This is perhaps most simply observed in relation to those with communication 'differences'. Dougall et al.,[61] within the context of SCD (Special Care Dentistry), highlight the poignant challenges encountered by individuals who through ill health, 'dis-ease' or genetic condition have their communication experience altered.

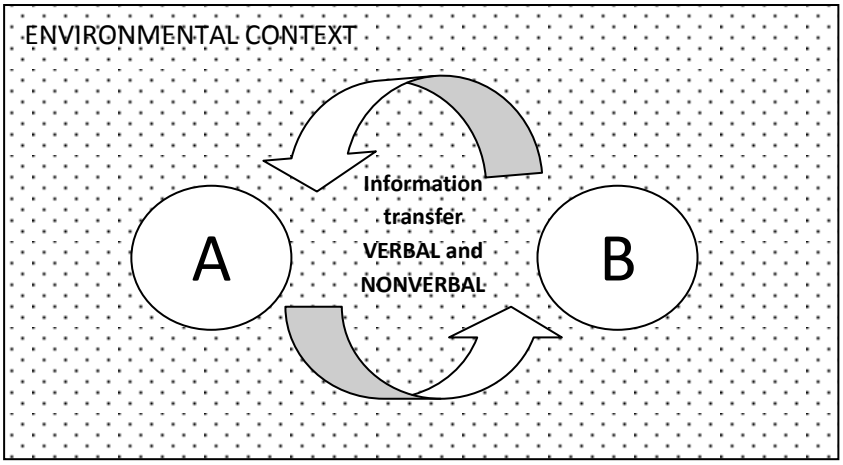
Zook,[62] an advocate for the biopsychosocial model[63] in Health Communication, considers this phenomenon as having two main pathways; a biochemical relationship and also a relationship involving psychological, social and cultural influences. [64,65]

In other words, 'dis-ease' can not only affect how an individual communicates but also how they are perceived by others, within the context of social and cultural norms.

2.2.6 The Dyad and the Healthcare Relationship

This interchange of information from one individual to another can be simply demonstrated using Barnlund's transactional model of dyadic interchange (see Figure 3).[66]

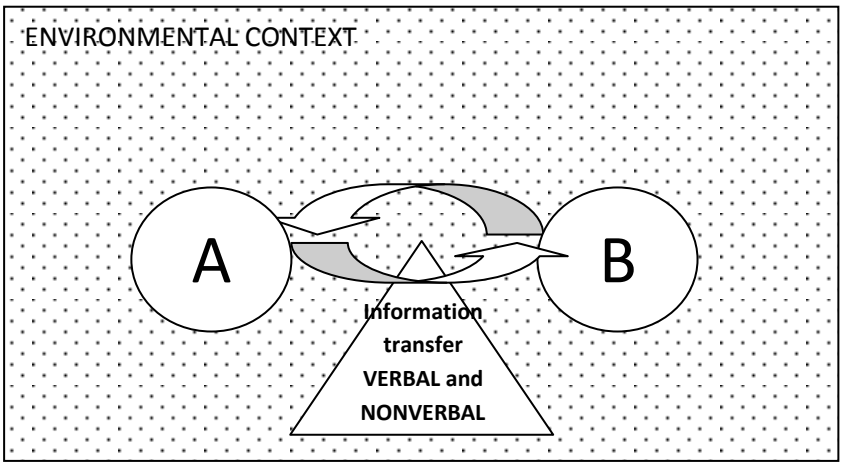
Figure 3: The Transactional Model: The Dyad



Here unlike previous communication models,[67, 68] both participating individuals (A and B) are shown to be involved in a dynamic, simultaneous process of message transfer and interpretation.

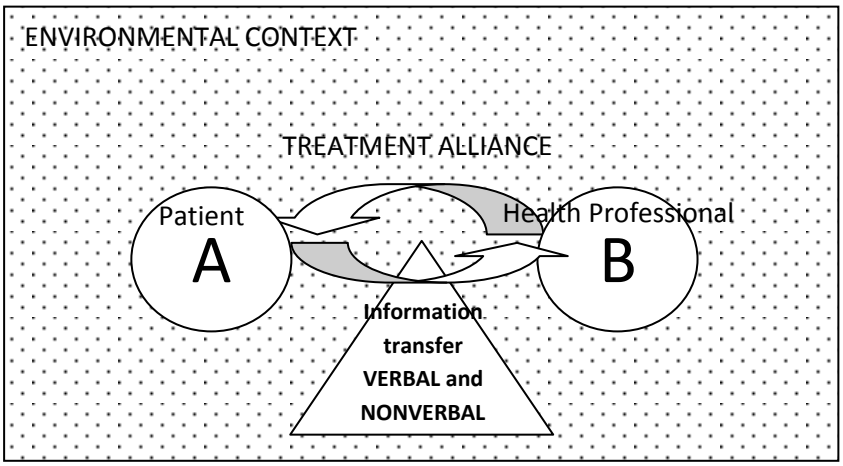
Barnlund,[66] by claiming that both participants are engaged in perpetual interaction, presents the dyad almost as a distinct functioning entity whose fulcrum or pivot point is the unimpeded information transfer between the individuals involved (see Figure 4). Thus supporting the theory that through balanced interpersonal relationship, 'meaning' may be created.[69]

Figure 4: Dyadic Balance



This balance in the relationship can also be viewed in relation to the concept of the treatment alliance.[70] Here, according to psychodynamic theory, participating individuals (patient and health professional) have an 'adult to adult' real relationship based on good communication and understanding (see Figure 5).[30, 71, 72]

Figure 5: The Therapeutic Relationship



It is this relationship, according to Buber's 'I-Thou' theory, that is built on the mutual participation of those involved.[73] Here individuals are presented as whole persons, bringing to the interaction their own life experiences, values and emotions that require the positive regard of the other, despite their differences. Balance in this case, is viewed through Buber's concept[73] of the 'narrow ledge' representing good communication based on mutual respect.

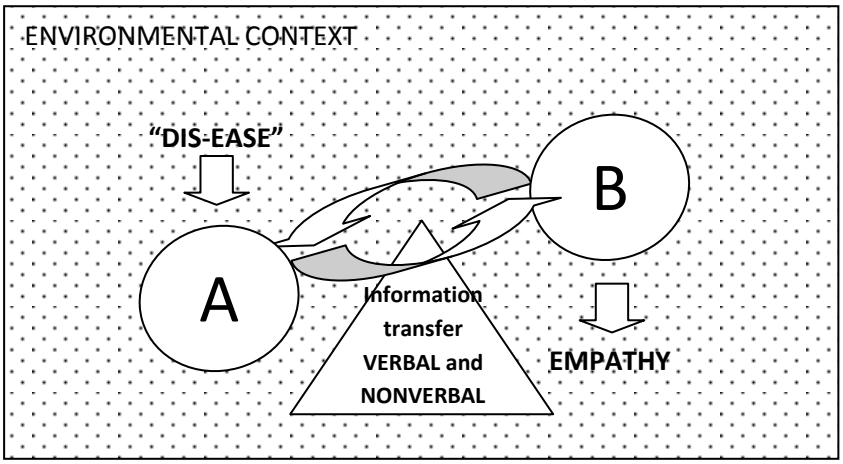
In healthcare, it is the understanding of such principals that have promoted the recent shift from Balint's 'patient-centred'[74] care to a more encompassing relationship-centred approach.[75] Here the authenticity of the interaction, based on good communication, is as important as the actual treatment received by the patient. Relationship-centred care according to Beach et al.,[76] is founded on four main principals:

1. Genuine relationships in healthcare are morally valuable.
2. Relationships in healthcare should include the personhood of those involved.
3. Healthcare relationships occur in the context of reciprocal influence.
4. Affect and emotion are important components of a healthcare relationship.

In other words, the key to relationship-centred care is not only mutual respect and understanding but also the ability to adapt to the communication style and emotional needs of others. This is of particular importance in cases where individuals have their communication ability altered due to 'dis-ease' as in the case of dental anxiety. In such cases, the health professional must be sensitive enough to perceive both verbal and non-verbal nuances of patient expression, enabling the continuation of the healthcare relationship.

This ability to support the patient by re-establishing balance in the dyad by effective communication is viewed by Rouse[1] as an expression of empathy (see Figure 6).

Figure 6: Dyadic Imbalance



By considering this theoretical standpoint that 'meaning' may be created through balanced dyadic interactions,[69] then the relationship between body and Health Communication (as discussed in Section 2.2.5) can be considered from an alternative viewpoint. If 'dis-ease' can affect an individual's experience of communication then it could be argued that dyadic communication and the quality of the resulting healthcare relationship, has the potential to reduce an individual's experience of 'dis-ease', i.e. dental anxiety.

2.2.7 The Dyad and Patient Health Outcome

The first tentative quantitative studies highlighting this alternative viewpoint, that the dyad may be able to influence patient outcome, appeared in the late 1960's. [77]

Initial studies considered the influence of direct 'patient-health professional' communication on patient satisfaction,[78] later developing to include patient adherence[79] and health outcome.[80]

This area of investigation within Health Communication, considering the relationship between dyadic communication and patient health outcome, plays on the so called tension between Health Communication and the body.

The effect of communication on patient health outcome, particularly within dyadic face to face patient-health professional interactions, has long been hypothesised, even from the birth of modern medicine.

> *"..the patient, though conscious that his condition is perilous, may recover his health simply through his contentment with the goodness of the physician"* [81]

This interaction, often termed 'good bed-side manner', is a concept in healthcare which according to Herbert et al., highlights "the relationship dimension of communication".[82] This relationship is the essence of 'effective communication' making both terms, in the author's opinion, equivalent. In other words, both 'good bed-side manner' and 'effective communication' describe a health professional's ability to influence a patient's health status by simply communicating care through a real empathic relationship. Although this connection has been widely suggested,[83, 84] there has been little empirical evidence to substantiate the claim.

The reason for this, according to Di Blasi et al.,[85] is that such communicative influences "tended to be controlled for rather than investigated" being "discounted as 'non-specific' or 'placebo'" in previous primary research studies.

One of the first attempts to scientifically collate and appraise research that directly addressed the influence of Health Communication on patient health outcome, was the systematic review undertaken by Stewart.[80]

This review chose wide inclusion criteria; discounting no study on patient age, medical specialty or study design (accepting both randomised controlled trials and 'analytic' studies).

All health outcomes were considered and communication interventions, both those focused on the patient (e.g. patient education) and health professional (e.g. communication training), were included. Despite restricting the search strategy to only one medical database (MEDLINE), the review identified 10 analytical or observational studies and 11 randomised controlled trials, with health outcomes including: emotional health, function, symptom resolution, pain control and physiological measures (e.g. blood pressure and blood sugar level).

Stewart[80] considered these studies according to the two main study design categories, in relation to whether the dyadic interchange was related to the initial part of the appointment i.e. 'patient history taking' or later in 'treatment management'. Any study which did not adhere to either group was considered under a third heading, that of 'other'.

Stewart[80] found that of the 21 studies included in the review, 16 reported positive results, four reported non-significant results and one study was inconclusive. Indeed in studies that focused on 'patient history taking', the majority (seven out of eight) demonstrated statistically significant changes in patient health outcome. Interestingly, Stewart[80] also noted that in those studies where the health professional received the communication intervention, patients' emotional status was affected whereas when it was the patient who received the intervention, a physical outcome was observed.

In relation to 'treatment management', both psychological and physiological health outcomes were noted in studies involving patient interventions, while health professional focused interventions again affected patient emotional status. The final group 'other' was found to have no clear outcome.

It should also be noted that no study in the Stewart[80] review considered interventions acting on both healthcare provider and patient. Nevertheless, the analytical studies reviewed by Stewart[80] identified a number of key communication behaviours which appeared to be significant in effecting a patient's health outcome (see Table 1).

Despite Stewart[80] highlighting a potential link between communication and emotional outcome, the review studies were poorly controlled. Subsequent reviews however aimed to address this short-coming by narrowing the design criteria to randomised controlled trials so that stronger conclusions about potential causation may be made.

The result, despite more rigorous methodology, has been that both the Di Blasi et al.,[85] and Griffin et al.,[86] reviews have been inconclusive, mainly due to the weak evidence base and varying study quality within the subject area.

Table 1: Elements of Effective Communication

History Taking: Effective Communication Elements		
	Element	Outcome
Physician	Asks questions to elicit patient perception of problem and understanding.	Effects patient anxiety and symptom resolution.
	Enquires about how patient feels.	Effects psychological distress
	Shows empathy.	Effects psychological distress and symptom resolution.
Patient	Able to fully express feelings and opinions.	Effects health status, functional status and blood pressure.
	Perceives that full discussion has taken place.	Effects symptom resolution.
Treatment Management: Effective Communication Elements		
	Element	Outcome
Physician	Gives clear information and support.	Effects psychological stress, symptom resolution and blood pressure
	Willing to share decision making.	Effects patient anxiety
	Agreement with patient regarding nature of problem and need to follow-up.	Effects problem and symptom resolution
Patient	Encouraged to ask questions	Effects anxiety and physical limitation
	Feels successful in acquiring the information wanted.	Effects functional and physiological status
	Receives information packs or programs	Pain, function, mood and anxiety.

Nevertheless, these reviews still suggest an underlying link between the quality of Health Communication, in the patient-health professional interaction, and patient health outcome.

This link is perhaps most striking when the data collated by both Stewart[80] and Griffin et al.,[86] is restricted to just one outcome, that of patient emotional status. The Di Blasi et al.,[85] review included studies where emotion was integrated into other outcome measures, hence anxiety could not be viewed alone.

Both reviews demonstrate a definitive change in the emotional status experienced by patients in almost all study intervention groups. Indeed, of the nine studies recorded as having an emotional or affective outcome only one had no significant outcome change within the intervention group. To date however, no review has considered patient emotional status as a distinct outcome of communication interventions. The author of this thesis has therefore conducted such a review as a separate study, reported in Section 2.3.

Based on the current evidence, the effect of Health Communication on patient health outcome, particularly in the realm of patient emotional status, requires further investigation.

Effective dyadic communication rather than being termed a 'placebo effect' may indeed be the active component in influencing a patient's emotional or affective outcome. This potential link between communication and affective outcome may be of particular importance within the context of Special Care Dentistry (SCD) and its subgroup, patient dental anxiety.

Dental Anxiety

> *"Fearful and phobic patients make up one important group of 'special needs [or special care] patients'. One special need that many patients have is the need to be treated in a way that diminishes the problem of dental fears."* [87]

2.2.8 Dentistry and Fear: The Relationship

Dentistry is a highly emotive form of healthcare.[1] Over the years, its association with potentially unpleasant procedures and emotions has made dental treatment synonymous in society with fear. Indeed, according to Peltier,[87] the 'frightened dental patient' has today become a cultural icon. Nevertheless, in an attempt to overcome these challenges, there has been a real move within the dental profession to not only understand patients' fears but also provide ways to help overcome them.[88, 89]

To consider ways of improving the emotional outcome for dental patients, it is important first to fully understand the root emotion, that of fear itself and its related concepts, anxiety and phobia.

2.2.9 Fear, Anxiety and Phobia: The Concepts

According to the Oxford English Dictionary, fear is "an unpleasant emotion caused by the threat of danger, pain or harm".[90] Despite originating from the Old English word 'fær' simply meaning 'an experience',[91] the concept of fear has a universally understood, deep emotive content.

Indeed, some of the most ancient human writings use the word fear to great emotive effect; the ancient Hebrew word for fear "yara" literally means a "flowing of the gut".[92] Yet fear, although associated with the unpleasant feelings generated by the sympathetic "flight-fright" response, is essentially a normal human reaction in the presence of danger. In other words, it is the rational response to a potentially harmful stimulus; with the fear dissipating as soon as soon as the danger is removed.[93]

In the case of anxiety, however, although it functions in a similar way to fear, it tends to be more diffuse, having the ability to be associated with events even when the original harmful stimulus has been removed.[94] This irrational association results in anxiety being present even when the original harmful stimulus, is not. Indeed, according to Locker,[95] anxiety is a rather "vague, unpleasant feeling accompanied by anticipation that something undesirable is about to happen".

To completely understand human anxiety however, a distinction must be drawn between its two main contexts; that of an individual's general state of mind and anxiety as a transient internal condition.[96, 97] In other words, from a biological perspective some individuals may experience anxiety as a 'state' or temporary feeling, while others experience anxiety as a 'trait' or component of their general personality.

Studies by Zeidner[98] and Endler et al.,[99] have shown a positive correlation between trait and state anxiety measures, suggesting that individuals with high trait anxiety may be predisposed to experiencing higher state anxiety.

Phobia may also be seen as an irrational response, in this case an "exaggerated fear".[100] Here the response is considered out of proportion to the actual stimulus. Phobia has been considered to be the result of the attachment of anxiety to the 'normal fear response' resulting in a self perpetuating emotional cycle,[101] Indeed, as the etymology of the word phobia suggests (originally from the Greek word "phobos" which means "flight")[102] individuals with phobias tend to go to great lengths to 'take flight from' or avoid their feared stimulus.[103]

In the dental literature the concepts of fear, anxiety and phobia in relation to a dental stimulus are often used interchangeably. However, it is the aim of this author to differentiate between these concepts and consider the two main so called "irrational" dental fears; that of dental anxiety and dental phobia.

2.2.10 Dental Anxiety and Dental Phobia

According to Freeman and Humphris, dental anxiety is "that feeling of apprehension experienced by an individual when confronted with matters that are dentally related".[104] First coined by Coriat in 1946, [105] dental anxiety like its root concept 'anxiety' is a complex human emotion with a multi-factorial aetiology [106] and diverse theoretical underpinning.[107]

Indeed, according to Coriat,[105] dental anxiety may be viewed from a psychodynamic perspective as "a true form of anticipatory anxiety". This anxiety is thought to result from an unresolved past experience, relived in the present dental appointment. Equally, however dental anxiety may also be conceptualised in relation to behavioural theory. Locker et al.,[108] studied dental anxiety within the context of a tripartite structure: a physiological response; a behavioural response and a cognitive response to dental treatment. These theoretical constructs are useful, in that they provide a way not only to explain the complex nature of dental anxiety but also help in differentiating it from dental phobia.[109]

Indeed, dental phobia according to psychodynamic theory occurs due to the establishment of a 'false connection'. Here, an individual's anxiety has not only been concentrated onto the dental treatment but has also been displaced from one situation to another.[110] Although dental phobia is intrinsically connected to dental anxiety it appears to be associated with the more extreme case where an avoidance state is created. Here, a patient may refuse to accept treatment due to the extreme nature of their fear.[111] According to Kulich et al.,[26] it is the very nature of this avoidance behaviour that makes extreme dental anxiety and dental phobia so significant, particularly in relation to its incidence.

> "*In contrast to many other phobias, [dental anxiety and dental phobia] sufferers are subjected to regular and repeated exposure to threatening stimuli or may be expected to do so. In addition, compared to most specific phobias, the feared situation is in many cases not avoided without significant consequences."* [26]

2.2.11 Prevalence of Dental Anxiety

According to the latest UK adult dental health survey, 12% of adults are fearful enough of dentistry to delay or even avoid dental attendance.[8] Such anxious behaviour has resulted in those who suffer from high levels of dental anxiety being regarded as amongst those with the poorest oral health-quality of life in Britain.[12]

Indeed, dental anxiety has been shown to be a significant barrier to dental care; with dentally anxious patients tending to have a greater numbers of missing teeth, fewer filled teeth and higher caries prevalence compared to their non anxious counterparts.[112] This in turn results in dentally anxious individuals having a higher dental treatment need.

Numerous studies have shown a variety of demographical factors associated with higher dental anxiety prevalence including age, gender and socioeconomic status.[113, 114, 115] Studies have not only demonstrated an association between increasing age and dental anxiety prevalence but also a gender association.[113]

Females tend, not only to claim higher levels of dental anxiety compared to males but studies have also shown a higher prevalence within this group.[114] Socioeconomic and education level factors[115] have also been shown however, evidence within this area has been inconclusive with some studies demonstrating no association.[116]

Nevertheless, dental anxiety has been shown to be of global significance. In a recent review of current literature Folayan et al.,[117] claimed worldwide dental anxiety prevalence ranging from 3 to 43%. Yet despite these current estimations, UK dental anxiety has decreased over the last five decades.[118]

Although it could be argued that this decrease may be due to the heterogeneity of dental anxiety outcome measures used over the years, it still highlights a trend thought to reflect the significant advances made in both dental technology and clinical technique.[3] Yet according to the Medical and Dental Defence Union of Scotland (MDDUS),[10] dental anxiety poses a real concern in medical-legal terms for today's clinicians.

According to a recent study by Hill et al.,[119] 91% of dentists reported feeling stressed when having to treat dentally anxious individuals. This in part, along with a need for better management skills, may be due to a lack of knowledge regarding a patient's actual level of anxiety.[120]

According to current guideline development from the Scottish Dental Clinical Effectiveness Programme,[15] dental anxiety measurements should be part of any oral health assessment and its resulting oral health risk. Yet despite this, in the study by Dailey et al.,[16] only 20% of general dental practitioners with an active interest in dental anxiety actually undertook such an assessment. This is a significant point, as it implies that clinicians are undertaking treatment unaware of the extent of an underlying clinically significant factor.

Indeed, identifying dentally anxious individuals and differentiating them from highly anxious and dentally 'phobic' patients, is clinically important not only in treatment planning but also in tailoring care to a patient's specific needs. In addition, the number of dentally phobic individuals will be somewhat less than those who are highly dentally anxious.

According to Freeman et al.,[121] it is the "amount of anxiety experienced in a quantitative sense which holds the "key" in distinguishing between individuals with dental anxiety and dental phobia.

As a means of differentiating between these emotional states, various tools have been developed as a way of quantifying the dental fear experienced.

2.2.12 Measuring Dental Anxiety and Clinical Relevance

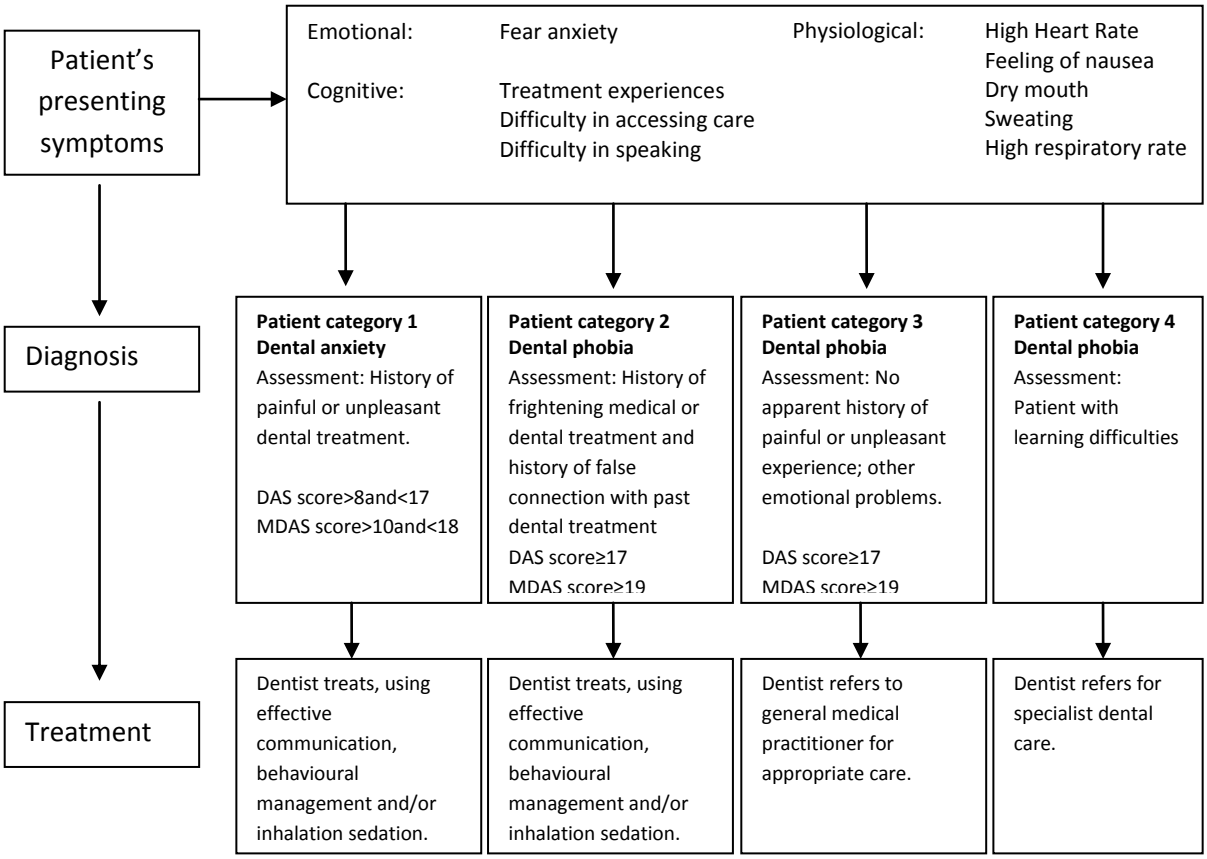
According to Newton et al.,[122] although many dental anxiety scales exist, the Corah Dental Anxiety Scale (DAS)[123] is the most widely used adult dental anxiety measure. Composed of four main questions, its narrow range of total scores and lack of local anaesthetic related question, has however associated it with limited clinical relevance.[124] In contrast, the Modified Dental Anxiety Scale (MDAS)[125] has shown not only good reliability and validity[126] but also a direct clinical relevance and acceptability.[16] Freeman highlights this relationship between quantifying dental anxiety and clinical management (Figure 7).[127]

Freeman[127] within this model proposes the clinical importance of distinguishing between various levels of anxiety in relation to dental clinical practice. Unfortunately in dentistry, focus is usually placed on completing treatment in spite of patient anxiety, with sedation and general anaesthesia used to suppress a patient's anxiety, allowing treatment to proceed.

In general terms, no attempt is made to address a patient's dental anxiety, only their dental need. Yet according to Rouse "patients seek both dental and emotional (anxiety reduction) treatment." [1]

Nevertheless, Rouse[1] claims that methods to reduce dental anxiety as part of that patient's holistic care are often seen to be out with the remit of everyday dental practice.

Figure 7: Classification of Dental Anxiety.[127]



It is therefore important to consider the various ways by which dental anxiety is currently managed in dental practice and the potential of apparent simple emotional interventions.

2.2.13 Dental Anxiety Management

A number of Cochrane protocols and published systematic reviews are currently available relating to the management of care for dentally anxious patients. Of the completed reviews that have been published, both consider the dentally anxious child patient, investigating the use of hypnosis and various sedation options as part of routine care. Both reviews were found to be inconclusive.[128, 129]

Protocols for reviews relating to conscious sedation[130] and psychological interventions in children[131] have also been submitted, with results pending. In the meta-analysis by Kvale et al.,[132] studies relating to behavioural interventions for dental anxiety and phobia showed significant, long-lasting reduction in dental fear. Of the 38 studies included in this review however, the majority considered interventions undertaken within a specialist dental fear clinical setting, requiring between six to 10 individual treatment sessions. The implication for such time consuming interventions within the context of the busy Primary Care dental practice is therefore limited.

Simple psychological interventions have also been considered. In the 2008 randomised controlled trial undertaken in Primary Care, Lahmann et al.,[133] highlighted the efficacy of brief relaxation techniques as a means of facilitating dental care highlighting short-term anxiety reduction in patients. Yet, if anxiety should be addressed as part of an individual's holistic care, then longer-term effects should be sought.

Indeed, Jöhren et al.,[134] showed that even after one year, a single session of psychological treatment could have continuing effects on the reduction of dental anxiety. This result was also confirmed by Berggren et al.,[135] in an earlier study.

De Jongh et al.,[136] also investigated the use of a single session intervention of "cognitive restructuring" as a means of influencing a patient's emotional outcome. The study claims a clear reduction in dental trait anxiety with a further substantial drop in anxiety after a period of one year.

Despite its obvious effect on patient anxiety, incorporating a one hour psychological intervention (as in the case of the De Jongh et al.,)[136] into busy dental practice would be clinically unfeasible.

In a more recent study by Weinstein et al.,[137] a simple two minute video providing dentally anxious children with information about "what an injection will feel like" and suggesting hand raising as a means of signalling to the dentist, found a significant fear reduction in the intervention group between pre and post anxiety scores. This suggests that providing information to the patient enhances their perceived control.

Information provision was also one of the key communication interventions highlighted in Stewart's 1995 systematic review[80] as being effective in altering a patient's health outcome. Although dentists have long since been aware of the need to communicate effectively with their patients, only one study, by Dailey et al.,[17] and a subsequent study by Hull et al.,[18] highlight its potential link with dental anxiety reduction.

Both studies by Dailey et al.,[17] and Hull et al.,[18] use the handing over of MDAS as the intervention in their randomised controlled trials set in Primary Dental Care. In the Dailey et al.,[17] study a significant reduction in dental state anxiety was recorded in patients who were randomised to the intervention group as opposed to those who completed the MDAS but did not hand it to the dentist.

The reason for this reduction was hypothesised by Dailey et al.,[17] to be either due to "(i) dentist behaviour/performance or (ii) patient expectancy". However limitations in the study design i.e. the lack of a parallel qualitative measurement, limited further investigation.

The results of the Hull et al.,[18] study expanded that of the original Dailey et al.,[17] study. The study was run in Access Centres in the North-west of England with participants who were mainly irregular dental attenders. In this case, a clinically significant reduction in patient dental state anxiety was shown to occur only when a "discussion" of dental anxiety (reported by the patient) had taken place. No relative reduction in dental anxiety was found in the patients who handed the MDAS questionnaire to the dentist when no "discussion" with the dentist occurred. This study, like that of Dailey et al.,[17] was unable to investigate the communication element further. Both studies therefore highlight a potential connection between communication and dental anxiety reduction as a patient health outcome. However, neither study was able to investigate the communication processes between the patient and the dentist during the dental visit. It was interesting to note that the staff involved in both these studies were mainly trained from the dental undergraduate level in the North-west of England which included training in MDAS and dental anxiety management from a psychological perspective.

2.2.14 Narrative Review Conclusion

In conclusion, and to summarise the main points made in this narrative review, it is proposed that the following statements underpin the evidence in relation to communication, anxiety and their interaction:

- Evidence shows that Health Communication is a complex phenomenon characterised by distinct intrinsic tensions, including the interplay of the body and communication.
- The body and Health Communication have been shown to be intrinsically connected; resulting in balanced interpersonal (dyadic) interactions having significant patient health outcomes. One such health outcome is on patient emotion i.e. anxiety.
- Patient dental anxiety is a form of anxiety that is particularly significant in dentistry and SCD.
- Patient dental anxiety can be reliably measured as a health outcome with associated clinical significance.
- The literature indicates a potential link between simple behavioural interventions and dental anxiety reduction.

It is therefore suggested that by using the main themes distilled in the narrative review it is possible to further develop the hypothesis put forward by both Dailey et al.,[17] and Hull et al.,[18] that the patient-dentist interaction in Primary Care (both verbal and non-verbal communication elements) may be responsible for decreasing patient state anxiety in MDAS handover.

That is, the interaction itself between that patient and dentist at the point, or soon after, the MDAS handover may influence patient response and reduce dental anxiety.

The dental profession, although aware of the need to establish good patient-dentist relationships requires more evidence relating to whether these relationships contribute to a reduction in dental anxiety as an emotional (affective) health outcome.

Investigating this interaction will not only continue to support the current view that effective communication is important but also that communication may be used as an effective treatment modality in holistic dental care.

2.3 Systematic Review

2.3.1 Introduction

Previous sections have reviewed the importance of Health Communication to patient outcomes and how part of this communication can influence patient emotional status, notably anxiety. A key emotion in the dental setting is dental anxiety and a key theme of this thesis is to ascertain how communication may affect dental anxiety.

The method employed in this Section, to investigate this focus, is a systematic review. According to Mulrow et al, [138]* systematic reviews are "explicit and rigorous methods to identify, critically appraise, and synthesize relevant studies". They look at the body of evidence as a whole, relating to a well defined research question, in an effort to produce the best reflection of what is 'the truth'. Such reviews must be strictly undertaken to minimise bias and optimise result reliability. This chapter aims to undertake a rigorous systematic review to (both develop and) answer the following research question:

"Does face to face communication with healthcare providers decrease patient anxiety and anxiety related health outcomes in adult Primary Care patients?"

This chapter has been divided into three phases: Phase One considers the development of the research question and protocol; Phase Two addresses how the literature search was undertaken; and finally Phase Three highlights the analysis and study results.

*__Please note__ both reference number and author's name will be used in this section for ease of reading.

2.3.2 Phase One: Developing the Research Question and Protocol

The main impetus for this review stems from the issue of whether communication with a healthcare provider, actually makes a difference to patient health, irrespective of the treatment being provided. This is a complicated issue with many potential influencing factors.

A clearly defined question was therefore required as a means of focusing the review to alleviate ambiguity. To develop such a question, a scoping literature search of MEDLINE was initially undertaken by the author. The aim was to establish a connection between face to face communication and patient health outcome.

An initial free-text search was undertaken in May/June 2009 using various combinations of text words, organised under four main subject categories:

1. Healthcare Provider
2. Patient
3. Communication
4. Health Outcome

Text words associated with each category were collated by the author. This was then used as the starting point for exploring the breadth of literature within the field of Health Communication. Various combinations of text words were used; one from each subject category, forming four word combinations linked by the Boolean 'AND'. The categories and their associated text words used in the initial free-text search are highlighted in Table 2.

Table 2: MEDLINE Free-Text Search*

Free Text category	Text words
Healthcare Provider	Healthcare professional, Healthcare provider, Health practitioner, Health visitor, Midwife, Doctor, Dentist, Dent*, Surgeon, Pharmacist, Nurse, Dental Nurse, Dental Therapist, Hygienist, Professionals Complimentary to Dentistry, PCDs, Primary Care, Secondary Care, Chiropodist, Podiatrist, Optician, Anaesthetist, Speech Therapist, Complimentary Practitioner
Patient	Consumer, Patient
Communication	Verbal, communication, Non-verbal, Paralinguistic, language, body language, behaviour, alliance, interaction, partnership, empowerment, patient-centred care, patient –provider relationship
Health Outcome	Health outcome

The author acknowledges that, in the development of initial search terminology and inclusion criteria, the use of a Focus Group would have been beneficial,[139] however due to restrictions in project timescale and funding, the incorporation of such an element was considered unfeasible.[140]

In this initial search of MEDLINE, PubMed was selected as the search engine for the database; only those documents highlighted by the search engine as 'reviews' were collated. A substantial number of reviews were identified, with 1,334 document abstracts and titles retrieved (in some cases only document titles were available).

This initial scoping free-text search highlighted the diversity of communication studies; from management to medicine, dyads to media; and from human to electronic.

The search not only provided the author with an awareness of the breadth of communication evidence but also the need for increased search precision to identify more relevant studies. The development of such a search strategy is highlighted in Phase Two of this Section.

Due to the diversity of the evidence retrieved using the initial free-text search, a number of search term definitions had to be developed. These definitions helped to establish a means of focusing the search area by considering the type of healthcare provider, patient, communication and outcome involved. These definitions are highlighted below in Table 3.

Table 3: Search Terms Definitions

Search Term	Definition
Healthcare provider	Individual responsible for the physical care of a patient.
Patient	Adult individual without any psychiatric illness
Communication	The face to face, verbal/non-verbal intervention that occurs between the patient and their health care provider.
Health outcome	A measurable physical or emotional change in patient health status

The 1,334 reviews were then assessed according to their title and abstract as to whether their elements reflected the developed search term definitions. These definitions were further enhanced by the development of exclusion criteria.

Reviews that included studies where all health professionals had formal psycho-analytical training prior to the start of the study e.g. psychologists, psychiatrists, psycho-analysts, therapists and counsellors, ensuring a higher degree of communication skills, were excluded. As were reviews where communication was defined as being between health professionals only; patients only; or indirectly mediated by computer or internet (including telemedicine).

Communication reviews that considered additional factors like cross-cultural or gender issues were also deemed outside the realms of the search. In addition, reviews that were limited to child participants only or those with psychiatric disorders were also excluded. A summary of the exclusion criteria is highlighted below in Table 4. It should be noted that in this initial search all health outcomes were considered.

Table 4: Exclusion Criteria for Reviews

Search Term	Excluded
Healthcare provider	Psychologist, psychiatrist, psycho-analyst, therapist, counsellor.
Patient	Children only and those with psychiatric disorders.
Communication	Computer-mediated, between Health Professionals only, between patients only, written communication elements only e.g. leaflets, internet, telecommunications, telemedicine, teaching, and cross cultural or cross-gender communication.
Health outcome	None

Following the removal of non-English papers, implementation of exclusion criteria and removal of duplicate references, 88 review abstracts remained. This number included reviews that could not be definitively excluded due to lack of information e.g. where only the title was available.

All 88 documents (see Appendix 2) were sourced and reassessed according to the search term definitions and exclusion criteria. At this stage, narrative review articles, primary research articles incorrectly indexed in MEDLINE, and reviews that only detailed theoretical communication models rather than empirical studies were excluded.

Only reviews that could be defined methodologically as 'systematic' were extracted for consideration. This was done by inputting the remaining document references into the Cochrane Library database.[141] The Cochrane Collaboration not only undertakes its own high quality reviews but also searches electronic databases including MEDLINE to extract methodologically sound review documents. These documents must meet the Collaboration's strict quality criteria so minimising bias. Only eight of the remaining documents were found in the Cochrane Library databases and therefore suitable for further consideration.

A snowballing technique was then used to include any other potentially valuable documents by assessing the reference lists of each of the eight included review papers. Any further reviews referenced in each bibliography were then extracted (n=29). Six duplicate documents were generated by this process, once they had been removed; the remaining additional reviews were then assessed according to the search term definitions and the exclusion criteria.

The remaining documents (n=9) were then inputted into the Cochrane Library as before. Of the nine documents considered, only five were indexed in the library. Two of the five remaining documents had already been sourced in the original eight reviews, so were excluded. The total number of new relevant systematic reviews found through considering the reference lists of eligible documents was therefore three.

This initial MEDLINE search and snowballing of the most relevant document references located 11 reviews to be studied by the author. Figure 8 highlights a flowchart of the initial MEDLINE search and selection process for extraction of these review documents.

The eleven reviews were then considered by the author in terms of establishing connection between face to face communication and patient health outcome. Only one review published in 1995 by Stewart,[80] demonstrated a correlation between effective physician-patient communication and improved health outcome. The remaining 10 reviews were either not investigating the relationship with health outcome or concluded that there was insufficient evidence to establish an effect. The components of each review are highlighted in Table 5; review protocol stipulations are detailed in the text while actual study content detailed alongside in bold italics.

The reviews were published between 1995 and 2007, appraising the body of communication literature ranging from 1966 to 2005. Eight of the 11 reviews clearly specified the inclusion of English language papers only, while one review by Griffin et al.,[86] specified no exclusion of studies on this basis.

Figure 8: MEDLINE Search and Selection Process.

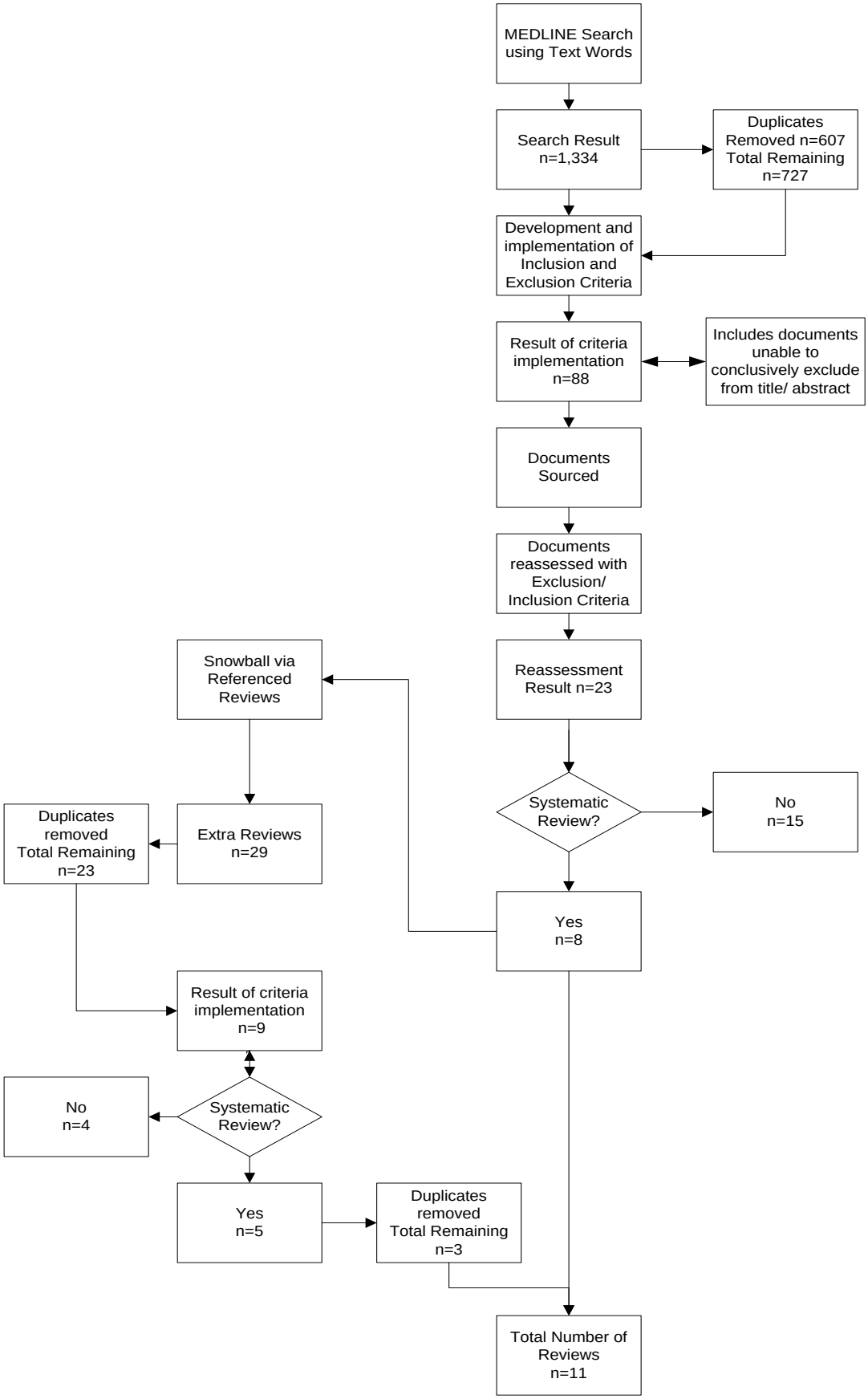


Table 5: Review of Systematic Reviews Extracted from Initial MEDLINE Search

Citation	Search	Study selection	Population	Intervention	Comparison	Outcome
Rao et al., 2007;Medical Care[142]	MEDLINE; EMBASE; CINAHL; PsycINFO; Social Sciences Index; CENTRAL. Conducted: 1966-2005 Feb. Reference list of eligible articles, review articles and textbooks used ENGLISH ONLY	PROTOCOL:RCTs ONLY (Randomised controlled trials) ***RESULT: as above***	PROTOCOL:MIXED SETTING No clinical setting was excluded. ***RESULT:(mainly Primary but also Secondary care)*** PROTOCOL:MIXED AGE Assuming no age group excluded. ***RESULT: as above***	Any designed to improve communication behaviour e.g. Information, feedback, modelling, practice. Studies included those conducted with physicians only, patients only or both. ***RESULT: as above***	VARIOUS: No intervention, placebo, equivalent communication intervention, non-equivalent communication interventions ***RESULT: as above***	Objective assessment of patient centred verbal communication of physician or patient No patient health related outcome ***RESULT: as above***
Michie et al., 2003;Patient Education and Counseling[143]	MEDLINE; PsycINFO; EMBASE; CINAHL; Web of Science Conducted: 1970-2000 Reference list of eligible articles and review articles. ENGLISH ONLY	PROTOCOL:MIXED Randomised controlled trials (RCTs); Quasi-experimental studies; longitudinal designs; cross-sectional study; descriptive study; qualitative studies. ***RESULT: as above***	PROTOCOL:MIXED SETTING ***RESULT: as above*** PROTOCOL:MIXED AGE Assuming no age group excluded. ***RESULT: as above (2 studies considered children only)***	Any study that measured patient-centeredness or any intervention that increased patient centeredness. All providers included. ***RESULT: as above***	PROTOCOL VARIOUS. ***RESULT: as above. Not all with comparisons, due to range of study designs included***.	Satisfaction Adherence Quality of life Physical health ***RESULT: as above***
McKinstry et al.,2006; Cochrane Database of Systematic Reviews[144]	MEDLINE (1966-2004); CENTRAL 2003); EMBASE (1985-2003 July); Health Star (1975-2004 July); PsycINFO (1967 to 2004 July); CINAHL (1982 to 2003 June); LILACS (1982-2003 April); African Trials Register (1948-2003 April); African Health Anthology (1924-2003 April); Dissertation Abstracts International (1861-2003 April). Reference list of eligible articles. Contacted researchers in the field.	PROTOCOL:MIXED Randomised controlled trials (RCTs);Quasi-experimental studies; ***RESULT: RCTs only***	PROTOCOL:MIXED SETTING No clinical setting was excluded. ***RESULT:PRIMARY CARE only*** PROTOCOL:MIXED AGE: (according to inclusion criteria all age groups accepted i.e. both adults and children) ***RESULT:ADULT only***	Any intervention to influence patients' trust directed at doctors or patients. All providers included. ***RESULT: Providers of interventions were physicians, a sociologist, nurses, and health educators***	PROTOCOL VARIOUS. ***RESULT: as above but only 3 RCTs included in the Review.***	Patient trust and components. Health care behaviour e.g. patient lifestyle behaviour. Health status measure. Use of resources Satisfaction with care Doctor/patient perceptions ***RESULT: Satisfaction; knowledge levels; referrals; diagnostic tests; disputes; helpfulness.*** ***No health status measures***

Citation	Search	Study selection	Population	Intervention	Comparison	Outcome
Griffin et al., 2004; Annuals of Family Medicine.[86]	MEDLINE (1966-1999); PsycINFO (1967-1999); HealthSTAR (1975-1999); Reference list of eligible articles ANY LANGUAGE	PROTOCOL:RCTs ONLY (Randomised controlled trials) ***RESULT: as above***	PROTOCOL:MIXED SETTING No clinical setting was excluded. ***RESULT:(mainly Primary but also Secondary care)*** PROTOCOL:MIXED AGE Assuming no age group excluded. ***RESULT: as above (children only study included)***	Interventions that alter interaction between patients and practitioners. ***RESULT: Providers of interventions were mainly practitioners.***	VARIOUS: No intervention, placebo, equivalent communication intervention, non-equivalent communication interventions ***RESULT: as above***	Patient satisfaction (included satisfaction with care, health service costs, knowledge and treatment adherence) Health Outcome: 1. Subjective (symptoms; anxiety, depression, functional status, well-being, quality of life, self reporting) 2. Objective (blood-pressure, blood glucose, video) ***RESULT: as above***
Harrington et al., 2004; Patient Education and Counseling.[145]	MEDLINE (1966-2001); PsycLIT (1966-2001); BIDS Social Science Citation Index (1981-2001); Reference list of eligible articles ENGLISH ONLY	PROTOCOL:MIXED Randomised controlled trials (RCTs); Quasi-experimental studies; and others. ***RESULT: RCTs, Quasi-experimental studies and 1 unclear study design.***	PROTOCOL:MIXED SETTING RESULT: as above PROTOCOL:MIXED AGE Assuming no age group excluded. ***RESULT: as above (1 studies considered children only)***	Any intervention designed to improve patients' communication with their doctors. ***RESULT: as above (included face to face; written; video; audio; multi-media***.	PROTOCOL VARIOUS. ***RESULT: as above. Control groups included Placebo, and non-intervention group, although one comparison was unclear.***	Adherence Satisfaction Knowledge Recall Response to illness Mood (anxiety measure) Attendance Disease control ***RESULT: as above***
Van Dam et al., 2003; Patient Education and Counseling.[146]	MEDLINE (1980-2001 Oct); EMBASE (1989-2001 Oct) PsycINFO (1980-2001 Oct); PsycLIT (1980-2001 Oct) Cochrane Library (from 1980-2001 Oct)) Reference list of eligible articles. ENGLISH ONLY	PROTOCOL:MIXED Randomised controlled trials (RCTs);Quasi-experimental studies only ***RESULT: RCTs only***	PROTOCOL:MIXED SETTING No clinical setting was excluded. ***RESULT: as above*** PROTOCOL:AGE UNCLEAR: ***RESULT: unclear***	Any intervention to modify provider-patient interaction, consulting style or patient education. All providers included. ***RESULT: Providers of interventions were physicians, nurses, patient groups, and telephone counselling.***	PROTOCOL VARIOUS. ***RESULT: as above***	Consultation behaviour Diabetes outcome Psychosocial ***RESULT: as above***

Citation	Search	Study selection	Population	Intervention	Comparison	Outcome
Mead et al., 2002; Patient Education and Counseling[147]	MEDLINE (1969-2000); PsycINFO (1969-2000); Reference list of eligible articles ENGLISH ONLY	PROTOCOL:UNCLEAR ***RESULT: Observational studies only***	PROTOCOL:PRIMARY CARE. ***RESULT: as above*** PROTOCOL:MIXED AGE Assuming no age group excluded. ***RESULT: mainly adult although one study grouped age 1 to 22years together.***	Studies of Patient-centeredness as defined by the authors, if quantitative measure available. ***RESULT: As above. Providers of interventions were mainly physicians or trainee doctors.***	PROTOCOL:VARIOUS: ***RESULT: no experimental studies included.***	Patient Centeredness ***RESULT: as above.***
Wilson et al.,2002; British Journal of General Practice[148]	MEDLINE (1966-1999 Nov); EMBASE (1981-1999 Nov) National Research Register (2000) Reference list of eligible articles Contacted researchers in the field. ENGLISH ONLY	PROTOCOL:OBSERVATIONAL ***RESULT: as above.***	PROTOCOL:PRIMARY CARE ***RESULT: as above*** PROTOCOL:MIXED AGE Assuming no patient age group excluded. ***RESULT: as above. Review mainly dealt with length of consultation not so interested in patient group.***	Studies that included average consultation length. ***RESULT: as above.***	PROTOCOL: None. ***RESULT: as above.***	Length of Consultation ***RESULT: as above.***
Lewin et al.,2001; Cochrane Database of Systematic Reviews[149]	MEDLINE (1966-1999 Dec); HealthSTAR (1975-1999 Dec); EMBASE (1985-1999 Dec) PsycLIT (1987-1999 Dec) CINAHL (1982-1999 Dec) Reference list of eligible articles. ENGLISH ONLY	PROTOCOL:MIXED Randomised controlled trials (RCTs) and Quasi-experimental studies. ***RESULT: as above***	PROTOCOL:MIXED SETTING No clinical setting was excluded. ***RESULT: mainly Primary Care.*** PROTOCOL:AGE UNCLEAR: ***RESULT: unclear***	Any intervention to encourage patient-centred care. ***RESULT: Providers of interventions were physicians and nurses who were trained in patient-centred consultation techniques.***	PROTOCOL VARIOUS. ***RESULT: as above.***	Consultation behaviour Empathy Patient satisfaction Health status ***RESULT: as above but few studies examined health status or behaviour.***

Citation	Search	Study selection	Population	Intervention	Comparison	Outcome
Di Blasi et al.,2001; Lancet.[85]	MEDLINE ;CENTRAL;CINHAL; Amed; PsycLIT; Sociofile; Social Science Citation Index; EMBASE; SIGLE; Dissertation abstracts Contacted researchers in the field.	PROTOCOL:RCTs ***RESULT: as above.***	PROTOCOL:MIXED SETTING ***RESULT: as above.*** PROTOCOL:MIXED AGE Assuming no age group excluded. ***RESULT: Unclear***	Studies where the patient-doctor interaction is considered as potentially effecting patient health outcome. ***RESULT: As above.***	PROTOCOL:VARIOUS: ***RESULT: as above.***	Objective or Subjective Health status Health service use, adherence to treatment, satisfaction, anxiety, treatment expectations, understanding illness, quality of relationship ***RESULT: as above***
Stewart, 1995; Canadian Medical Association Journal.[80]	MEDLINE (1983-1993); Reference list of eligible articles Conference proceedings reviewed. ENGLISH ONLY	PROTOCOL:MIXED ***RESULT: RCTs and observational studies.***	PROTOCOL:MIXED SETTING ***RESULT: as above.*** PROTOCOL:MIXED AGE ***RESULT: as above.***	Interventions that improved communication approaches ***RESULT: as above.***	PROTOCOL: VARIOUS ***RESULT: as above***.	Patient Health outcome: Physiological; functional; symptom resolution and emotional status. ***RESULT: as above***

The selection of studies to be included in each review varied, with six specifying inclusion of both randomised and quasi-experimental studies (detailed in Table 5 as 'mixed studies'), three randomised controlled trials only and one included observational studies (one review was unclear as to its study specification). In practice however, two of the mixed reviews contained only randomised controlled trials (McKinstry et al.,[144] and Van Dam et al.[146]). Four of the five reviews that only contained randomised controlled trials, stipulated that a search of CENTRAL or the Cochrane Library had been undertaken.

In terms of setting, most reviews accepted studies undertaken in Primary, Secondary or Tertiary Care (n=9) with only two reviews limiting inclusion to primary care studies. Despite accepting studies from all settings, four of the nine reviews that originally stipulated a mixed setting, contained only or mainly studies from Primary Care.

All 11 reviews did not exclude studies based on age of their participants therefore including both adults and children. Only one review contained studies with exclusively adult participants, although this review by McKinstry et al.,[144] was based on just three randomised control trials so reducing the population group substantially.

No exclusion on format of intervention was used in any of the 11 reviews undertaken; including written patient leaflets, videos, and multimedia. The interventions were either implemented on healthcare professionals to improve their communication/ patient centeredness skills or on the patient to improve their involvement in the consultative process. Various types of healthcare professional were involved but tended to be nurses and physicians. No limitation on comparison was made by any of the eleven reviews.

The outcomes recorded by each review varied substantially. Seven of the eleven reviews included studies that considered a change in the patient's physical health while six reviews included a summary of patient satisfaction with care. Emotional status or mood was considered by five of the eleven reviews with three reviews specifically highlighting anxiety as a secondary outcome. By understanding the contents of previous reviews the author aimed to develop a definitive framework for developing a research question.

Although most studies concluded that insufficient evidence was available to demonstrate a relationship between face to face communication and health outcome, the author hypothesised that by focusing on one main outcome and structuring the review research question to strengths in the available evidence, a more precise question could be developed. The author therefore considered each research element (the population, intervention, comparison, and outcome) to identify current evidence base gaps, as well as strengths in the available literature.

In terms of population and setting, Primary Care seemed to contain the bulk of Health Communication studies although it was only stipulated in two of the eleven reviews. This setting would therefore be a feasible element in the inclusion criteria for study acceptance into the review. A review question developed to focus on Primary Care would also have greater applicability compared to one including studies from all settings.

Randomised controlled trials appeared numerous within this field so restricting inclusion to studies with this design would not only be achievable but would also increase the quality of the end review.

Age ranges within each of the eleven reviews varied with only one containing adults exclusively. Having an age limit as part of the inclusion criteria was considered by the author to be an essential element in understanding the interaction between patient and healthcare provider. The setting of a suitable age range would prevent potentially relevant studies being excluded. According to Cramer et al.,[150] reviews vary in how they define 'a child', with some reviews including individuals of as young as 14 years in their adult population.

Due to the fact that all eleven of the communication reviews used a mixed age sample, the author decided to define a child, in terms of the research question, as individuals younger than 16 years.

Although a range of interventions were considered in the eleven reviews, no review stipulated purely a face to face interaction. The author highlights this as a limiting factor in the inclusion of studies in this review. The specification of face-to-face interaction in a new review was considered important to limit the variety of contexts of how interactions can be delivered. All available comparisons would be considered, mirroring the eleven reviews highlighted by the initial MEDLINE search, although one specific outcome would be assessed.

No review considered anxiety as a primary outcome, yet this element was often highlighted by review authors as an area for future study.[85]

From these elements the author therefore established a definitive research question and protocol for the resulting review.

2.3.2(i) The Developed Research Question and Summary Protocol

Research Question: **"Does face to face communication with healthcare providers decrease patient anxiety and anxiety related health outcomes in adult Primary Care patients?"**

Methods: Criteria for selecting studies for the review:

- Types of studies: Randomised Controlled Studies only.
- Setting of studies: Primary care.
- Types of participants: Adult participants (16 years and over) with no psychological illness.
- Types of interventions: Face to face communication interactions between healthcare providers and patients only.
- Types of Outcomes Measurable patient anxiety outcome.

Initial MEDLINE search exclusion criteria (Table 6) would also be implemented.

Table 6: Exclusion Criteria from Initial MEDLINE Search

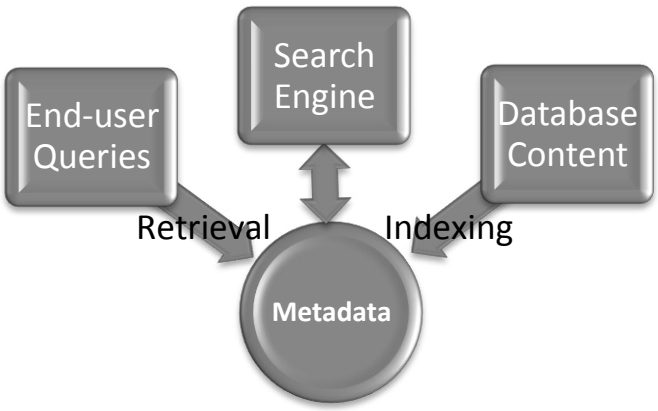
Search Term	Excluded
Health care provider	Psychologist, psychiatrist, psycho-analyst, therapist, counsellor.
Patient	Children only and those with psychiatric disorders.
Communication	Computer-mediated, between Health Professionals only, between patients only, written communication elements only e.g. leaflets, internet, telecommunications, telemedicine, teaching, and cross cultural or cross-gender communication.
Health outcome	None

This protocol was used as the basis for the development of Proforma One (Article Exclusion Questions); Proforma Two (Article Inclusion Form) and Proforma Three (Article Exclusion Form) detailed in Phase Three of this Chapter.

2.3.3 Phase Two: Developing the Search Strategy

The initial scoping free-text search of MEDLINE identified the need for increased precision in search methodology. To do this, an understanding of the field of Information Retrieval (IR) was required. Information Retrieval, a term coined by Mooers in 1951, [151] deals with the indexing and retrieval of principally textual information providing access to a vast array of records. Having an understanding of the basic concepts of IR, provides focus in developing a deliberate search strategy that can find relevant documents even through "data smog". [152] A model of the IR system is highlighted below in Figure 9.

Figure 9: The Information Retrieval (IR) System



Adapted from Hersh[153]

This model illustrates how an end-user can access the content of a database e.g. MEDLINE by inputting queries to the system. Content information can then be retrieved by matching Metadata (i.e. indexing terms and attributes) which are the same in both the query and the document.

This matching process is done via the search engine. Different databases not only use different search engines but also use different indexing methods or ways of assigning metadata to content.

Generally there are two indexing formats: controlled vocabulary which is assigned by a professional indexer, describing in essence what a document is about e.g. Medical Subject Headings (MeSH used in MEDLINE) and EMTREE (used in EMBASE), which use hierarchical tree-like systems to structure headings according to specificity, as highlighted in Figure 10; and the second involves extraction of words in the database by computer e.g. free-text searching. This initial search of MEDLINE only used the latter method so resulting in a more random approach to the search strategy.

Figure 10: Example of MeSH Tree Structure (2009)

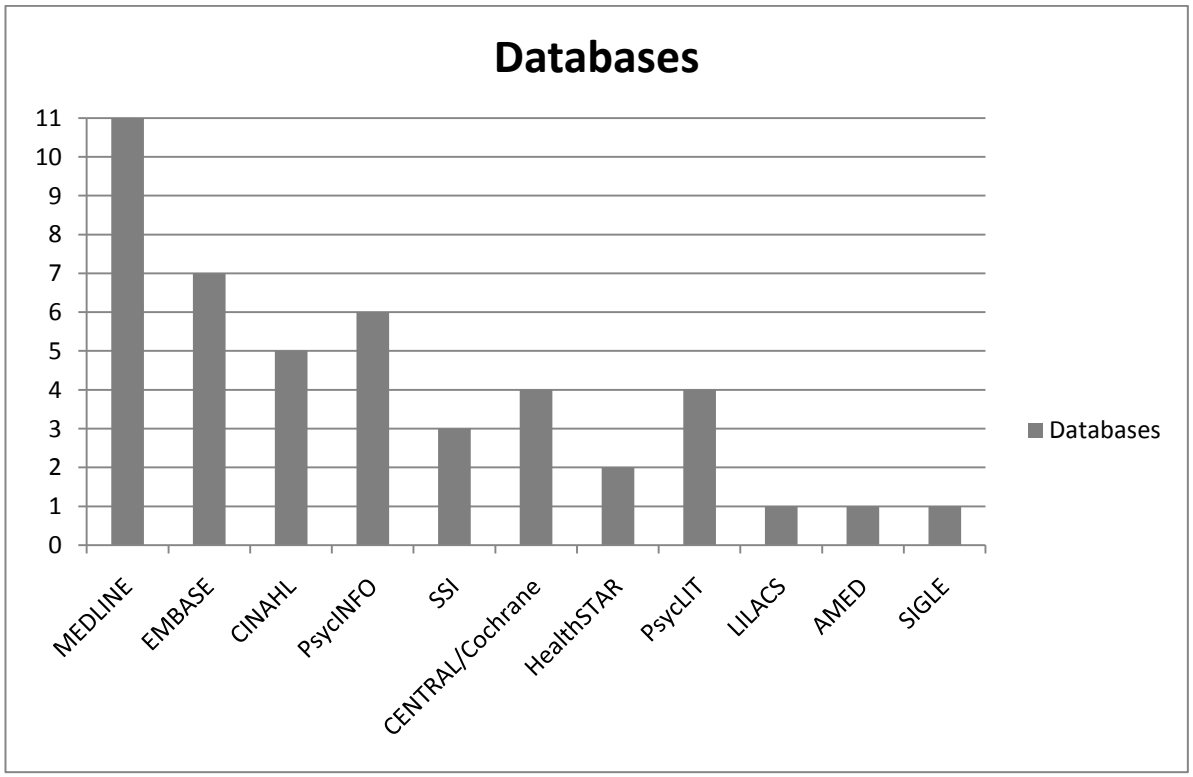
Communication
- Advertising as Topic
- Answering Services
- Communication Barriers
- Computer Literacy
- Cybernetics
- Diffusion of Innovation
- Hotlines
- Information Dissemination
- Interdisciplinary Communication
- **Language**
  - Language Arts
  - **Linguistics**
    - Terminology as Topic
    - Phonetics
    - **Psycholinguistics**
      - **Neurolinguistic Programming**
- Negotiating
- Non Verbal Communication
- Persuasive Communication
- Propaganda
- Reminder Systems

Searches can be limited to one part of the MeSH Tree for a specific search or by exploding a MeSH term a more generalised search can be undertaken

The author therefore used the results of the initial MEDLINE search as a platform to develop a more concise search strategy. This was conducted by examining the search methodology of previously published relevant reviews: the databases included in their search strategy; the filters implemented; and the free-text and controlled vocabulary headings used. All strategies would then be compared to the standards set out in the Cochrane Handbook for Systematic Reviews. [154]

Searches of the available evidence base reported by the original eleven reviews included a variety of databases. The number of electronic databases used in each of the reviews varied from one (Stewart[80]) to 10 (McKinstry et al.,[144]). All included a systematic search of MEDLINE. Figure 11 highlights the range and frequency of the main databases used in the eleven reviews.

Figure 11: Main Databases used in included Systematic Reviews



Of these reviews only four undertook a search of the CENTRAL database or Cochrane Library. It should be noted that all reviews that included a search of the Cochrane Library contained studies of only randomised controlled trials (n=4). Due to the current protocol's stipulation for RCTs, the author therefore aimed to utilise this information by employing the Cochrane databases as the platform for initiating the new search.

The Cochrane databases contain both reviews (secondary research) and primary research (randomised controlled trials). The RCTs are located in the CENTRAL database. This database is composed of records extracted from MEDLINE and EMBASE as well as those found by hand searching and from specialised registers. This makes this database not only comprehensive but also due to Cochrane's strict study inclusion criteria, a source of high quality literature.

Despite this, all four reviews that used a CENTRAL/Cochrane Library search employed MEDLINE as their main search database, duplicating or minimising the search year filter for CENTRAL. According to the Cochrane Collaboration, this is duplication of work. For this reason, CENTRAL was chosen as the main search database by the author, while MEDLINE and EMBASE databases would be used for supplemental searches using Cochrane's recommended filters for RCT extraction.

According to Cochrane "It is recommended that for all Cochrane Reviews, CENTRAL and MEDLINE should be searched, as a minimum, together with EMBASE if it is available".[155] It is recommended that if a full CENTRAL search is undertaken that MEDLINE should be searched from 2005 onwards while EMBASE should be searched for the "most recent two years".[155]

As CENTRAL only contains RCTs, no filter is needed to identify suitable study types, however in MEDLINE and EMBASE a diverse collection of study designs are present. Specifically designed search filters that identify RCTs must therefore be used to focus the search strategy. These filters can either optimise search sensitivity or search precision. The bulk of studies highlighted by the sensitivity search gives an indication of the need to apply the precision maximising filter. The filters used in this search are highlighted below in Tables 7, 8 and 9.

Table 7: The Cochrane Highly Sensitive Search Strategy for Identifying Randomised Trials in MEDLINE: Sensitivity-Maximising Version (2008 Revision); PubMed Format[156]

#1	Randomized controlled trial [pt]
#2	Controlled clinical trial [pt]
#3	Randomized [tiab]
#4	Placebo [tiab]
#5	Drug therapy [sh]
#6	Randomly [tiab]
#7	Trial [tiab]
#8	Groups [tiab]
#9	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8
#10	Animals [mh] NOT humans [mh]
#11	#9 NOT #10

Table 8: The Cochrane Highly Sensitive Search Strategy for Identifying Randomized Trials in MEDLINE: Sensitivity and Precision-Maximizing Version (2008 Revision); PubMed Format[156]

#1	Randomized controlled trial [pt]
#2	Controlled clinical trial [pt]
#3	Randomized [tiab]
#4	Placebo [tiab]
#5	Clinical trials as topic [mesh: noexp]
#6	Randomly [tiab]
#7	Trial [ti]
#8	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7
#9	Animals [mh] NOT humans [mh]
#10	#8 NOT #9

Table 9: EMBASE Free Text and Controlled Vocabulary (EMTREE) Terms used to identify RCTs

Free-Text Terms	EMTREE Terms
Random$	Crossover-procedure
Factorial$	Double-blind procedure
Crossover$	Randomized controlled trial
Cross over$	Single-blind procedure
Cross-over$	
Placebo$	
Doubl$ adj blind$	
Singl$ adj blind$	
Assign$	
Allocate$	
Volunteer$	

2.3.3(i) Developing the Search Words

Following the results of the first scoping search using the text-words collated by the author and consideration of existing review contents; the research question highlighted in the protocol was further focused using the PICO method. This would form the basis to the search strategy.

Population: Adult patients in Primary Care.

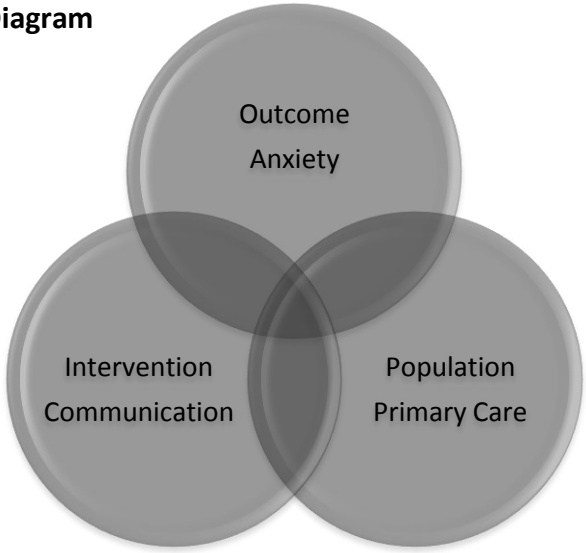
Intervention: Face to face communication between healthcare provider and patient.

Comparison: All comparisons would be considered.

Outcome: Change in measured anxiety level and anxiety related health outcomes.

A Venn diagram (see Figure 12) was then used to focus the main components of the study question. These components were used and combined using the Booleans 'AND' and 'OR' as the basis for the search strategy. The Boolean 'NOT' was excluded from the search strategy as this would mean the exclusion of references that contained both an 'OR' and a 'NOT' term. To ensure increased sensitivity the search strategy would not include all three components initially but focus mainly on the outcome i.e. anxiety and the intervention i.e. face to face communication. The population component (i.e. adult patients in Primary Care) could then be added at the end of each search to control the amount of literature highlighted. Specifying control interventions within the search would not be used so to accept all possible control formats again this was done to maintain a sensible balance between the specificity and the sensitivity of the search strategy.

Figure 12: Venn-Diagram



The main components were further developed by establishing synonymous lists of search terminology both text-words and controlled vocabulary under each component heading. The text-words associated with communication were collated from the search methodologies used by the eleven systematic reviews highlighted in the previous section. This therefore provided not only tried and tested methodology but also peer accredited terminology. The terms are highlighted in Table 10.

Text-words were further modified according to nuances in spelling e.g. English/American (this is highlighted in italics). According to the Cochrane ethos reviews should be both extensive and systematic. This means that both text-words and controlled vocabulary should be used. Controlled vocabularies are essentially key terms used to index articles according to perceived themes. The problem with this form of indexing is its subjectivity, meaning that some articles may be indexed incorrectly especially where important words appear in the full text version but not in the abstract title. A combination of both forms of indexing is therefore needed for input into the system to retrieve as many relevant documents as possible.

Table 10: Text-Words and Controlled Vocabulary for Search Strategy

Component	Subject Heading	Synonyms and Search Terms	
		Controlled Vocabulary (MeSH)	Text-words terms
Outcome	Anxiety	[FEAR] exploded, includes dental anxiety and panic. [STRESS, PSYCHOLOGICAL] [INHIBITION, PSYCHOLOGICAL] [FEEDBACK, PSYCHOLOGICAL]	[Anxiety OR anxious OR fear* OR Phobia] [STAI-S OR MDAS OR (anxiety NEXT measurement) OR (Modified NEXT Dental NEXT Anxiety NEXT Scale) OR (State NEXT Trait NEXT Anxiety NEXT Inventory NEXT State)] [(Heart NEXT Rate) OR Pulse], [Blood NEXT Pressure], [(Failed OR Missed) NEXT appointment*]
Intervention	Communication	[COMMUNICATION] exploded in tree one. [PROFESSIONAL-PATIENT RELATIONS] exploded both trees. [PATIENT-CENTRED CARE] [PRIMARY HEALTH CARE] [APPOINTMENTS AND SCHEDULES] [POWER, PSYCHOLOGY]	Communic* [Communic* NEXT (behaviour OR healthcare OR skills)] [Verbal NEXT (communic* OR behaviour)] [Non-verbal NEXT (behaviour OR communic*)] [body NEXT language] OR language OR paralinguistic [(Medical OR Patient) NEXT history NEXT taking) OR consultation* OR interview*] [Patient NEXT (empower*OR education OR centred OR *cent*red* OR particip* OR involvement OR alliance OR compliance)] [(Physician OR professional OR doctor OR Nurse OR dentist OR provider) NEAR patient NEAR (relation* OR communic* OR Interaction OR partnership OR negotiat*)]

The general search strategy using both controlled vocabulary and free-text terms is highlighted in Table 11. The strategy is based around the combination of terms relating to the outcome (anxiety) and relating to the intervention (communication).

This strategy forms the basis for the CENTRAL, MEDLINE and EMBASE searches although some alteration was required due to nuances in database terminology.

Table 11: The General Structured Search Strategy

		Search Terminology
Intervention: Communication	#1	[COMMUNICATION] explode in tree one.
	#2	[PROFESSIONAL-PATIENT RELATIONS] explode both trees
	#3	[PATIENT-CENTERED CARE] explode in all three trees
	#4	[PRIMARY HEALTH CARE] explode in tree one
	#5	[APPOINTMENTS AND SCHEDULES] explode in tree one
	#6	[POWER, PSYCHOLOGY] explode in tree one
	#7	Communic*
	#8	[Communic* NEXT (behaviour OR healthcare OR skills)]
	#9	[(Verbal OR Non-verbal) NEXT (behaviour OR communic*)]
	#10	[(body NEXT language) OR language OR paralinguistic]
	#11	[(Medical OR Patient) NEXT history NEXT taking) OR consultation* OR interview*]
	#12	[Patient NEXT (empower*OR education OR cent*red OR particip* OR involvement OR compliance)]
	#13	[Therapeutic NEXT alliance]
	#14	[(Physician OR professional OR doctor OR Nurse OR dentist OR provider) NEAR patient NEAR (relation* OR communic* OR Interaction OR partnership OR negotiat*)]
	#15	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14
Outcome: Anxiety	#16	[FEAR] explode tree one, includes dental anxiety and panic.
	#17	[STRESS, PSYCHOLOGICAL] explode in both trees
	#18	[INHIBITION, PSYCHOLOGICAL] explode in all three trees
	#19	[FEEDBACK, PSYCHOLOGICAL] explode in tree one
	#20	[PSYCHOPHYSIOLOGY] explode in all four trees (includes neurophysiology)
	#21	[Anxiety OR Anxious OR Fear* OR Phobia]
	#22	[STAI-S OR MDAS OR (anxiety NEXT measurement) OR (Modified NEXT Dental NEXT Anxiety NEXT Scale) OR (State NEXT Trait NEXT Anxiety NEXT Inventory NEXT State)]
	#23	[(Heart NEXT Rate) OR Pulse]
	#24	[(Blood NEXT Pressure) OR Physiology OR Neurophysiology]
	#25	[(Failed OR Missed) NEXT appointment*]
	#26	#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25
	#27	#15 AND #26

The actual searches undertaken in the three databases and the resulting number of papers highlighted are demonstrated in the following pages. Initially the entire Cochrane Library was searched in November 2009 and the total number of relevant papers at each stage of the search highlighted (see Table 12).

Table 12: Results of the Cochrane Search Strategy

ID	Search	Hits
#1	MeSH descriptor **Communication** explode tree **1**	3089
#2	MeSH descriptor **Professional-Patient Relations** explode all trees	1413
#3	MeSH descriptor **Patient-Centered Care** explode all trees	160
#4	MeSH descriptor **Appointments and Schedules** explode all trees	528
#5	MeSH descriptor **Power (Psychology)** explode all trees	85
#6	(Communic*):ti,ab,kw	5028
#7	(Communic* NEXT (behaviour OR healthcare OR skill*)):ti,ab,kw	347
#8	(Non-verbal OR verbal) NEXT (behaviour OR communic*):ti,ab,kw	762
#9	(body NEXT language) OR language OR paralinguistic:ti,ab,kw	3111
#10	(Medical OR Patient) NEXT history:ti,ab,kw or (Consultation* OR Interview*):ti,ab,kw	11046
#11	(Patient NEXT (empower* OR education OR cent*red OR particip* OR involvement OR alliance OR compliance)):ti,ab,kw	14933
#12	(therapeutic NEXT alliance):ti,ab,kw	133
#13	(Physician OR professional OR doctor OR Nurse OR dentist OR provider) :ti,ab,kw and (patient OR consumer):ti,ab,kw and (relation* OR communic* OR Interaction OR partnership OR negotiat*):ti,ab,kw	4013
#14	(**#1** OR **#2** OR **#3** OR **#4** OR **#5** OR **#6** OR **#7** OR **#8** OR **#9** OR **#10** OR **#11** OR **#12** OR **#13**)	34573
#15	MeSH descriptor **Fear** explode all trees	903
#16	MeSH descriptor **Stress, Psychological** explode all trees	2378
#17	MeSH descriptor **Inhibition (Psychology)** explode all trees	237
#18	MeSH descriptor **Feedback, Psychological** explode all trees	145
#19	MeSH descriptor **Psychophysiology** explode all trees	25475
#20	(Anxiety OR Anxious OR Fear* OR Phobia):ti,ab,kw	16522
#21	(anxiety NEXT measurement):ti,ab,kw or (MDAS OR (Modified NEXT Dental NEXT Anxiety NEXT Scale)):ti,ab,kw or (STAI-S OR (State NEXT Trait NEXT Anxiety NEXT Inventory NEXT State)):ti,ab,kw	36
#22	(Heart NEXT Rate) OR Pulse:ti,ab,kw	32495
#23	(Blood NEXT Pressure) OR Physiology OR Neurophysiology:ti,ab,kw	74419
#24	(Failed OR Missed) NEXT appointment*:ti,ab,kw	26
#25	(**#15** OR **#16** OR **#17** OR **#18** OR **#19** OR **#20** OR **#21** OR **#22** OR **#23** OR **#24**)	114407
#26	(**#14** AND **#25**)	7314
#27	MeSH descriptor **Primary Health Care** explode all trees	2640
#28	(community AND care):ti,ab,kw	3893
#29	(primary NEAR care):ti,ab,kw	6199
#30	(#27 OR #28 OR #29)	9651
#31	(#26 AND #30)	592
#32	#31 AND adult*: ti.ab.kw	327

Table Key: ti= Title; ab= Abstract; kw= Keyword

Due to the large number of abstracts available at stage #26 of the search, the author implemented the third element of the Venn-diagram i.e. population and included the Primary Care setting. Following the implementation of the reviews' search term definitions and exclusion criteria as detailed in the protocol, 11 papers remained.

The search methodology for MEDLINE using the search engine PubMed incorporated the RCT filter that maximized precision. Initially the sensitivity filter was used but due to the vast quantity of abstracts retrieved (580,625 in November 2009) this had to be altered to make the amount of abstracts more manageable. The MEDLINE search (from the beginning of 2005 till Nov 2009) is detailed below (see Table 13) and includes stipulation on population and setting. In total 411 abstracts were retrieved in November 2009, of which 36 were reviews, leaving a total of 375. Following the implementation of search term definitions and exclusion criteria this was condensed to 11 papers.

Table 13: The MEDLINE Search Strategy

primary care and AND ((("2005"[Publication Date] : "3000"[Publication Date]) AND (((randomized controlled trial[pt]) OR (controlled clinical trial[pt]) OR (randomized[tiab]) OR (placebo[tiab]) OR (clinical trials as topic[mesh:noexp]) OR (randomly[tiab]) OR (trial[ti])) NOT (animals[mh] NOT humans[mh]))) AND ((("2005"[Publication Date] : "3000"[Publication Date]) AND ((fear[mh]))) OR ((stress, psychological[mh]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((feedback, psychological[mh]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((psychophysiology[mh]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((anxiety[tiab]) OR (anxious[tiab]) OR (fear*[tiab]) OR (phobia[tiab]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((anxiety measurement[tiab]) OR (MDAS[tiab]) OR (modified dental anxiety scale[tiab]) OR (STAI-S[tiab]) OR (state trait anxiety inventory scale[tiab]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((heart rate[tiab]) OR (pulse[tiab]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((blood pressure[tiab]) OR (physiology[tiab]) OR (neurophysiology[tiab]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((blood pressure[tiab]) OR (physiology[tiab]) OR (neurophysiology[tiab]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((failed appointment*[tiab]) OR (missed appointment*[tiab]) AND ("2005"[Publication Date] : "3000"[Publication Date]))) AND (((communication[mh]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR

((professional patient relations[mh]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((patient centered care[mh]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((primary health care[mh]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((appointments and schedules[mh]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((communic*[tiab]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((communic* AND behavior[tiab]) OR (communic* AND healthcare[tiab]) OR (communic* AND skills[tiab]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((verbal communic*[tiab]) OR (non-verbal communic*[tiab]) OR (verbal behavior[tiab]) OR (non-verbal behavior[tiab]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((body language[tiab]) OR (language[tiab]) OR (paralinguistic[tiab]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((medical history[tiab]) OR (patient history[tiab]) OR (consultation[tiab]) OR (interview[tiab]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((patient empower*[tiab]) OR (patient education[tiab]) OR (patient centered[tiab]) OR (patient particip*[tiab]) OR (patient involvement[tiab]) OR (patient alliance[tiab]) OR (patient compliance[tiab]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR ((therapeutic alliance[tiab]) AND ("2005"[Publication Date] : "3000"[Publication Date])) OR (((physician[tiab]) OR (professional[tiab]) OR (doctor[tiab]) OR (nurse[tiab]) OR (dentist[tiab])) AND ((patient[tiab]) OR (consumer[tiab])) AND ((relation[tiab]) OR (communic*[tiab]) OR (interaction[tiab]) OR (partnership[tiab])) AND ("2005"[Publication Date] : "3000"[Publication Date])))))

The EMBASE search was undertaken using the search engine OVID. The search used the filter for extraction of RCTs recommended by the Cochrane Collaboration. The search was also restricted to the most recent two years (2007 till Nov 2009 inclusive). The search strategy is detailed in Table 14, retrieving 402 abstracts. Following the implementation of the search definitions and exclusion criteria this was reduced to seven papers.

Table 14: The EMBASE Search Strategy

1. (random$ or factorial$ or crossover$ or cross over$ or cross-over$ or placebo$ or (doubl$ adj blind$) or (singl$ adj blind$) or assign$ or allocat$ or volunteer$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
2. limit 1 to yr="2007 -Current"
3. (crossover-procedure or double-blind procedure or randomized controlled trial or single-blind procedure).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
4. limit 3 to yr="2007 -Current"

5. 2 or 4

6. exp human relation/

7. limit 5 to yr="2007 -Current"

8. exp professional practice/

9. limit 8 to yr="2007 -Current"

10. exp general practice/

11. limit 10 to yr="2007 -Current"

12. exp patient satisfaction/

13. limit 12 to yr="2007 -Current"

14. exp health care delivery/

15. limit 14 to yr="2007 -Current"

16. exp health care quality/

17. limit 16 to yr="2007 -Current"

18. exp doctor patient relation/

19. limit 18 to yr="2007 -Current"

20. exp interpersonal communication/

21. limit 20 to yr="2007 -Current"

22. exp patient care/

23. limit 22 to yr="2007 -Current"

24. exp health care/

25. limit 24 to yr="2007 -Current"

26. exp consultation/

27. limit 26 to yr="2007 -Current"

28. exp patient compliance/

29. limit 28 to yr="2007 -Current"

30. exp medical information/

31. limit 30 to yr="2007 -Current"

32. exp empowerment/

33. limit 32 to yr="2007 -Current"

34. exp patient attitude/

35. limit 34 to yr="2007 -Current"

36. exp patient education/

37. limit 36 to yr="2007 -Current"

38. 7 or 9 or 11 or 13 or 15 or 17 or 19 or 21 or 23 or 25 or 27 or 29 or 31 or 33 or 35 or 37

39. communic$.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]

40. limit 39 to yr="2007 -Current"

41. ((communic$ adj Behaviour) or (communic$ adj healthcare) or (communic$ adj skills)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]

42. limit 41 to yr="2007 -Current"

43. ((verbal adj communic$) or (verbal adj behavior) or (non-verbal adj behavior) or (non-verbal adj communic$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]

44. limit 43 to yr="2007 -Current"

45. ((body adj language) or language or paralinguistic).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]

46. limit 45 to yr="2007 -Current"

47. ((medical adj history) or (patient adj history) or consultation$ or interview$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]

48. limit 47 to yr="2007 -Current"

49. ((patient adj empower$) or (patient adj education) or (patient adj centered) or patient particip$ or patient involvement or patient alliance or patient compliance).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]

50. limit 49 to yr="2007 -Current"

51. therapeutic alliance.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]

52. limit 51 to yr="2007 -Current"

53. ((physician or professional or doctor or nurse or dentist or provider) and (patient or consumer) and (relation or communic$ or interaction or partnership or negotiat$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]

54. limit 53 to yr="2007 -Current"

55. 40 or 42 or 44 or 46 or 48 or 50 or 52 or 54

56. exp fear/

57. limit 56 to yr="2007 -Current"

58. exp mental stress/

59. limit 58 to yr="2007 -Current"

60. exp "inhibition (psychology)"/

61. limit 60 to yr="2007 -Current"

62. exp adaptive behavior/

63. limit 62 to yr="2007 -Current"

64. exp psychophysiology/

65. limit 64 to yr="2007 -Current"

66. (anxiety or anxious or fear$ or phobia).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]

67. limit 66 to yr="2007 -Current"

68. ((anxiety adj measurement) or MDAS or (modified adj dental adj anxiety adj scale) or STAI-S or (state adj trait adj anxiety adj inventory adj scale)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]

69. limit 68 to yr="2007 -Current"

70. ((heart adj rate) or pulse).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]

71. limit 70 to yr="2007 -Current"

72. ((blood adj pressure) or physiology or neurophysiology).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]

73. limit 72 to yr="2007 -Current"

74. 57 or 59 or 61 or 63 or 65 or 67 or 69 or 71 or 73

75. 38 or 55

76. 5 and 74 and 75

77. primary care.mp. or exp primary medical care/

78. limit 77 to yr="2007 -Current"

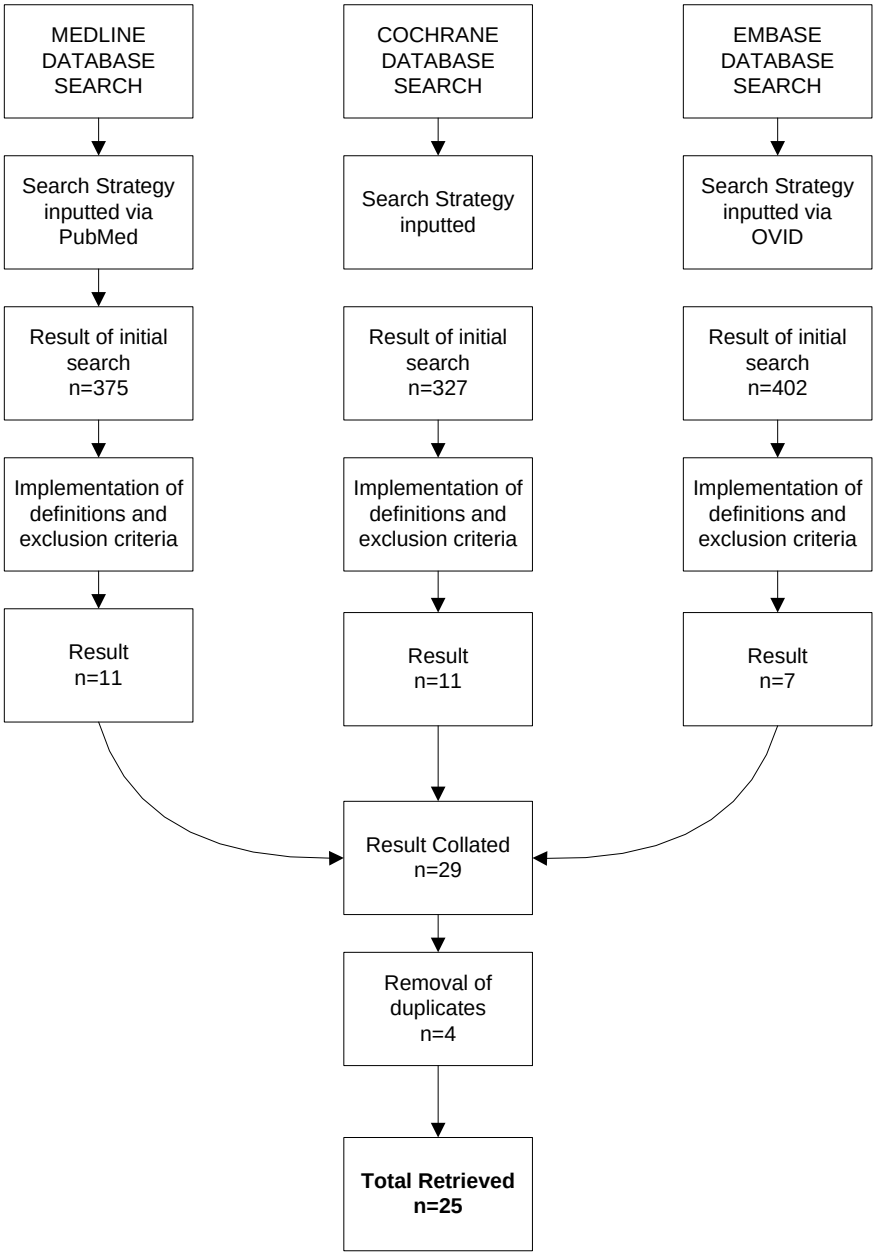
79. 76 and 78

The entire search process is summarised in the flowchart shown in Figure 13. It highlights the stages to the search and the resulting collaboration of the search results, culminating in 25 primary research papers that could be considered for inclusion into the review (see Appendix 3).

The final phase of this chapter highlights the selection of the studies included in the review and the extraction and analysis of results in relation to the question:

"Does face to face communication with healthcare providers decrease patient anxiety and anxiety related health outcomes in adult Primary Care patients?"

Figure 13: Summary of Literature Search Methodology



2.3.4 Phase Three: Analysis and Study Results

Twenty-five papers reporting primary research studies were identified from the systematic literature search in Phase Two. Phase Three allows a more detailed examination of the identified literature so that the research question may be answered using the most appropriate studies. In this chapter the process of final study selection, data extraction and analysis is considered.

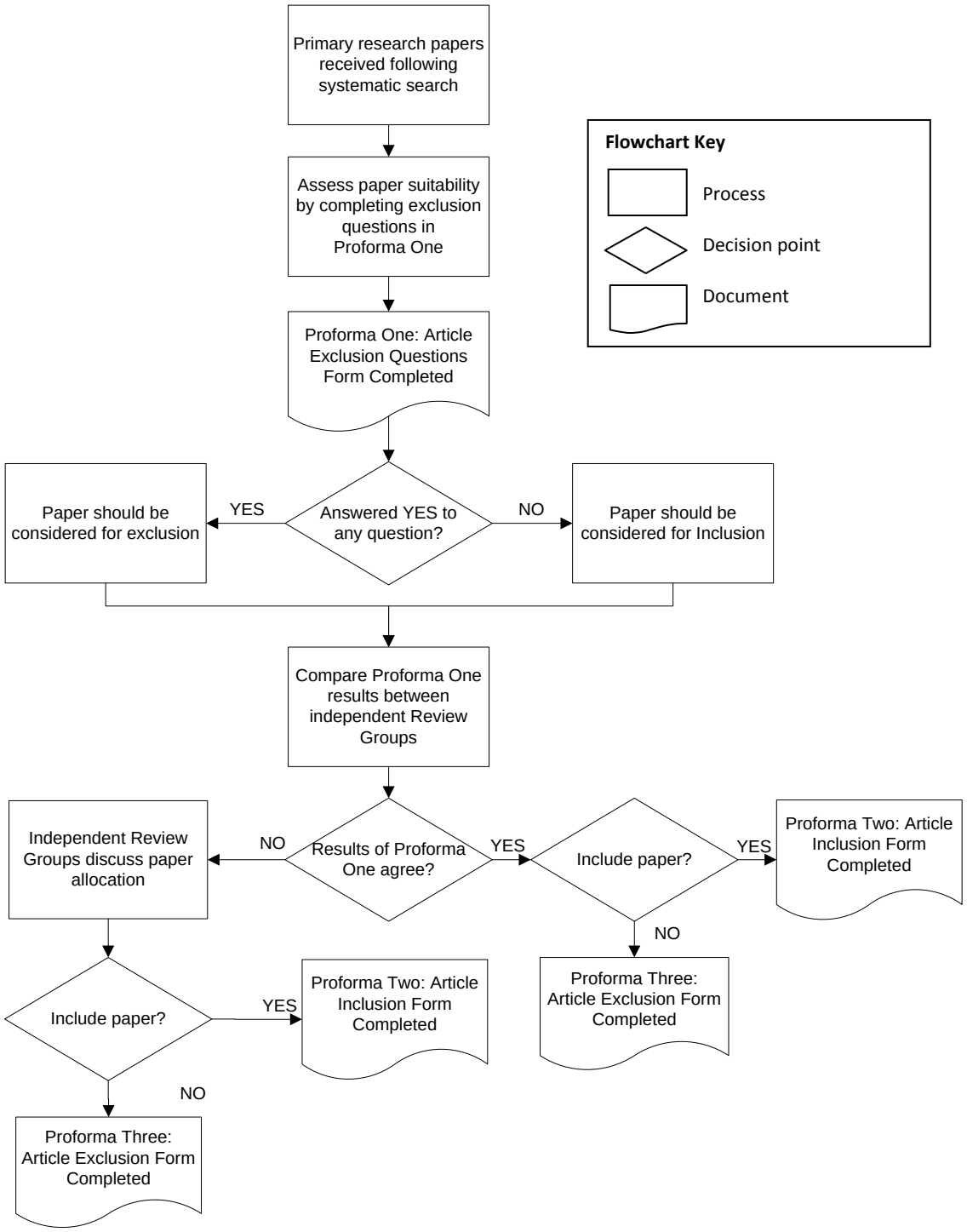
Initially each of the studies identified in Phase Two were assessed for suitability of inclusion into the final systematic review. This was done by two independent reviewer groups set up to consider the studies contained in each paper. The groups considered the papers in relation to a predetermined review process developed by the author in conjunction with the review protocol (Figure 14).

The process involved the completion of three systematic review forms or Proformae. These forms are highlighted in Appendix 4:

1. Proforma One: Article Exclusion Questions form
2. Proforma Two: Article Inclusion form
3. Proforma Three: Article Exclusion form

Each reviewer group completed Proforma One for studies in all 25 primary research papers. The completion of this initial Proforma allowed the groups to independently consider and provisionally include or exclude each paper. This was done by studying the paper contents in relation to a set of questions summarised in Proforma One. When the group answered ‘Yes’ to any of the form’s ten questions then the study could be considered for exclusion from the final systematic review.

Figure 14: The Review Process to be followed by Reviewer Groups



The questions contained in Proforma One, are highlighted below:

1. Is the paper in a language other than English?
2. Is the article other than original data?
3. Is the study's design other than a randomised controlled trial?
4. Is the study setting other than Primary Care?
5. Are the patients involved in the study younger than 16 years old?
6. Do any of the patients involved in the study have psychological problems?
7. Is the communication in this study only between healthcare providers?
8. Is the communication in this study only indirect in nature?
9. Does the communication involve psychologists, psychoanalysts, therapists or counsellors?
10. Does the study exclude an anxiety measure?

On completion of Proforma One, the groups' results were compared. The two groups either agreed or disagreed, as to whether a paper and hence a study should be excluded or included into the systematic review. In cases where the two groups agreed, the study followed the agreed allocation. In cases however, where the groups disagreed, the papers were brought to an intergroup forum where both groups discussed the merits of including or excluding the study contained in the paper.

Of the 25 papers highlighted in the systematic literature search, the two groups independently agreed to exclude eight papers and include five papers. The remaining 12 papers and their included studies were brought to the intergroup forum for group discussion.

Of these papers, 10 were excluded from the final review while two were deemed to have enough merit to be included; the two groups reached consensus on all papers brought into the intergroup forum. Table 15 summarises individual group and intergroup discussion results regarding paper and hence study allocation.

Following analysis of Proforma One results, the two groups agreed to eliminate eighteen primary research papers from the final systematic review. In each case when a paper was excluded based on the ten Proforma One questions, the article exclusion form, Proforma Three was completed. The completed forms produce a record of the reasoning behind paper rejection, and hence study elimination from the review process.

Following the exclusion of the 18 papers, seven of the original 25 primary research studies remained. These more relevant studies would be analysed further for possible inclusion and in an attempt to ensure that no additional studies were overlooked; a snowballing technique was used to assess the reference sections of each of the seven papers.

Out of a total of 326 references contained by the seven papers, 28 titles were deemed worthy of further consideration. The abstracts of each of the 28 papers were assessed in relation to the inclusion criteria stipulated in the study protocol. Studies that could be definitively excluded from the review at this stage were eliminated (n=17).

Table 15: Summary of the Results from Proforma One and Intergroup Discussion

Paper No.	First Author	Independent Reviewer Result			Group Discussion: Include?
		Reviewer 1 *	Reviewers 2 & 3 **	Include?	
1	Van Bokhoven et al.,[157]	Included	Included	☑	N/A
2	Helmes et al.,[158]	Excluded	Included	?	☒
3	Izzo et al.,[159]	Included	Exclude	?	☒
4	Little et al.,[160]	Excluded	Included	?	☒
5	Alamo et al.,[161]	Included	Included	☑	N/A
6	Ridsale et al.,[162]	Excluded	Included	?	☒
7	McLeod et al.,[163]	Excluded	Excluded	☒	N/A
8	Pålsson et al.,[164]	Excluded	Excluded	☒	N/A
9	Roter et al.,[165]	Included	Included	☑	N/A
10	Serwint et al.,[166]	Excluded	Included	?	☒
11	Girgis et al.,[167]	Excluded	Included	?	☒
12	Koelewijn-van Loon et al.,[168]	Included	Included	☑	N/A
13	Kravitz et al.,[169]	Excluded	Excluded	☒	N/A
14	Copello et al.,[170]	Included	included	☑	N/A
15	Brown et al.,[171]	Excluded	Excluded	☒	N/A
16	Heritage et al.,[172]	Excluded	Included	?	☒
17	Gall et al.,[173]	Excluded	Excluded	☒	N/A
18	Lövander et al.,[174]	Excluded	Excluded	☒	N/A
19	Wattchow et al.,[175]	Excluded	Excluded	☒	N/A
20	Stuckey et al.,[176]	Excluded	Included	?	☑
21	Haskard et al.,[177]	Excluded	Included	?	☒
22	Lauritzen et al.,[178]	Excluded	Included	?	☑
23	Farmer[179]	Excluded	Included	?	☒
24	Kulzer et al.,[180]	Included	Excluded	?	☒
25	Bakker et al.,[181]	Excluded	Excluded	☒	N/A

*Reviewer 1 was the author and made up Reviewer Group One

**Reviewer 2 was Prof Ruth Freeman and Reviewer 3 was Prof Gerry Humphris making up Reviewer Group Two

Studies that appeared to fit the inclusion criteria or could not be definitively excluded were sourced in their entirety and reviewed according to Proforma One by the two reviewer groups. Eleven papers were assessed by the groups. Following final intergroup consultation only three papers were deemed suitable for potential inclusion into the final systematic review (Table 16).

Table 16: Summary of Snowball Results from Proforma One & Intergroup Discussion

Snowball (SB) Paper No.	First Author	Independent Reviewer Result			Group Discussion: Include?
		Reviewer 1 *	Reviewers 2 & 3 **	Include?	
SB1	Peck et al.,[182]	Excluded	Excluded	☒	N/A
SB2	Jung et al.,[183]	Excluded	Excluded	☒	N/A
SB3	Thompson et al.,[184]	Included	Included	☑	N/A
SB4	Moral et al.,[185]	Excluded	Excluded	☒	N/A
SB5	Johnson et al.,[186]	Excluded	Excluded	☒	N/A
SB6	Thomas[187]	Excluded	Excluded	☒	N/A
SB7	O'Connor et al.,[188]	Excluded	Excluded	☒	N/A
SB8	Gabbay et al.,[189]	Excluded	Excluded	☒	N/A
SB9	Kaplan et al.,[190]	Excluded	Excluded	☒	N/A
SB10	Putnam et al.,[191]	Excluded	Included	?	☑
SB11	Evans et al.,[192]	Included	Included	☑	N/A

*Reviewer 1 was the author and made up Reviewer Group One

**Reviewer 2 was Prof Ruth Freeman and Reviewer 3 was Prof Gerry Humphris making up Reviewer Group Two

All the papers considered by the reviewer groups to be potentially suitable for inclusion (seven from the initial 25 primary research papers and three from the snowballing process) were collated for Proforma Two completion (n=10).

Proforma Two extracts detailed data from each paper regarding the elements of its contained study or studies. Information about participant profile; study methods; quality of the study (via the Cochrane Collaboration's Tool for Assessing Risk of Bias); study intervention; outcomes; results; and key conclusions were documented as part of the inclusion process. In some cases an individual paper may not contain enough information about a study to proficiently complete Proforma Two. In such cases the author identified further information from external publication sources; as individual studies may be reported in more than one paper.[193] In some cases, this additional information, raised questions about the study's continued suitability for inclusion. In such cases the study was brought to the intergroup forum for discussion and allocation consensus.

Completion of Proforma Two also highlighted key issues in study methodology that would otherwise have been overlooked during Proforma One completion. Proforma Two therefore allows study elements to be laid bare and inaccuracies to be identified. In cases where inaccuracies in study methodology were highlighted, papers were brought back to the intergroup forum for discussion and possible reallocation. Table 17 summarizes the final decision process.

The full review process highlighting the stages where papers were eliminated from the review is highlighted in Figure 15. All papers eliminated from the review either initially or in the late stages of the process had Proforma Three completed. Proforma Three results are summarized in Appendix 5.

Table 17: Summary of Definitive Paper Inclusion, Reallocation and Exclusion

Paper No.	First Author	No. Studies per Paper	Additional Information Required?	Reallocation on Proforma Two completion?	Definitive Allocation
1	Van Bokhoven et al.,[157]	1	Yes [194]	No	Include
5	Alamo et al.,[161]	1	No	No	Include
9	Roter et al.,[165]	1	No	No	Include
12	Koelewijn-van Loon et al.,[168]	1	No	No	Include
14	Copello et al.,[170]	1	No	Yes	Exclude
20	Stuckey et al.,[176]	1	No	Yes	Exclude
22	Lauritzen et al.,[178]	1	Yes[195]	Yes	Exclude
SB3	Thompson et al.,[184]	2	No	No	Include
SB10	Putnam et al.,[191]	1	No	Yes	Exclude
SB11	Evans et al.,[192]	1	No	No	Include

Following the final selection process, six papers remained for data extraction and analysis of results (Table 18). For each paper, an article inclusion form (i.e. Proforma Two) was completed, this allowed for the extraction of relevant information from each of the reported studies to be undertaken. One of the included papers, Thompson et al.,[184] reported more than one research study. In this case, each of the two studies contained in the paper had a Proforma Two completed.

Figure 15: Summary of Actual Review Process

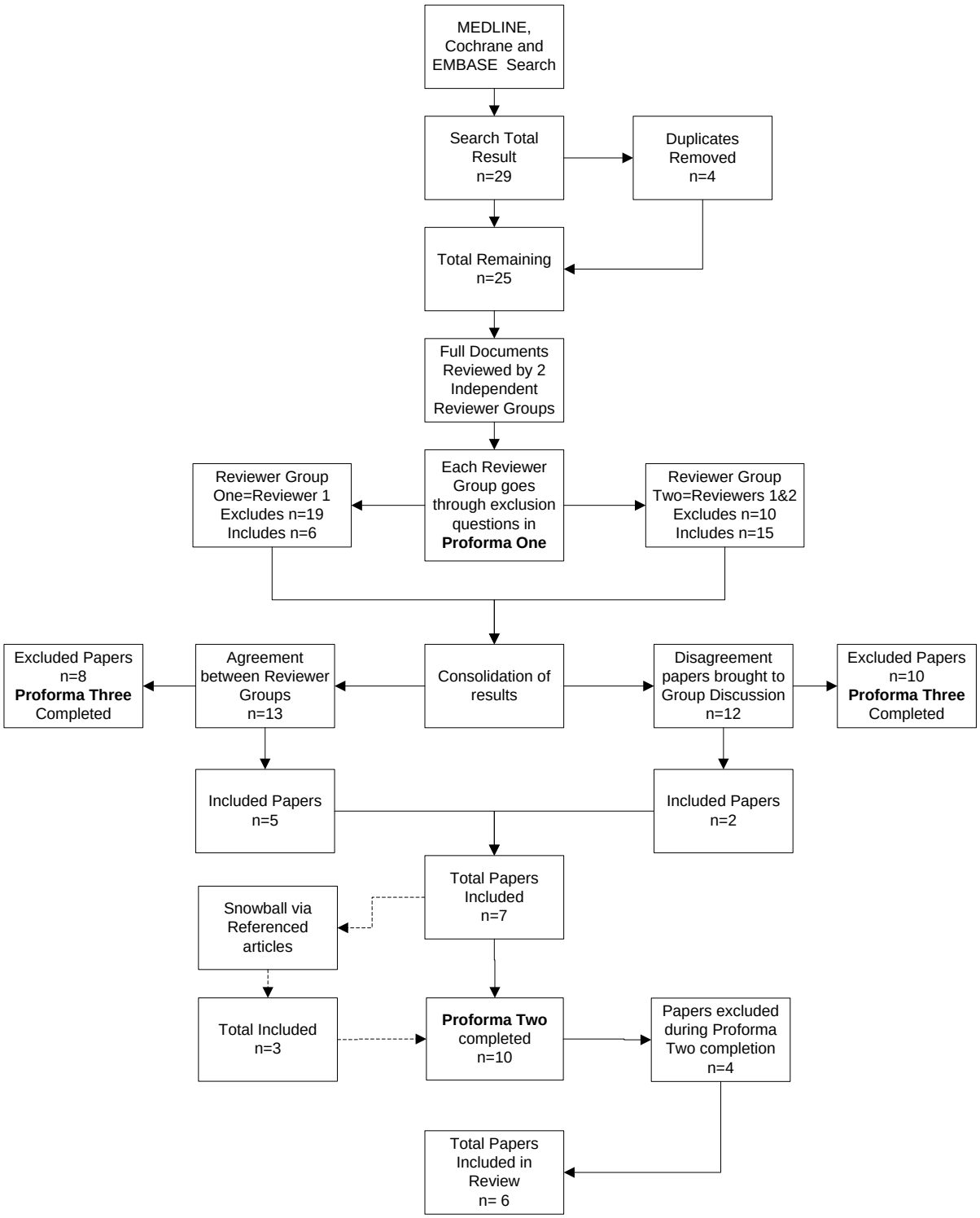


Table 18: Included Primary Research Papers

Paper No.	First Author	Title
1	Van Bokhoven et al.,[157]	Influence of watchful waiting on satisfaction and anxiety among patients seeking care for unexplained complaints
5	Alamo et al.,[161]	Evaluation of a patient-centred approach in generalized musculoskeletal chronic pain/fibromyalgia patients in primary care
9	Roter et al.,[165]	Improving physicians' interviewing skills and reducing patients' emotional distress
12	Koelewijn-van Loon et al.,[168]	Improving lifestyle and risk perception through patient involvement in nurse-led cardiovascular risk management: A cluster-randomized controlled trial in primary care
SB3	Thompson et al.,[184]	Patient-oriented interventions to improve communication in a medical office visit
SB11	Evans et al.,[192]	A communication skills programme for increasing patients' satisfaction with general practice consultations

It is these six papers containing seven studies that will be used in an attempt to answer the original Systematic Review research question:

"Does face to face communication with healthcare providers decrease patient anxiety and anxiety related health outcomes in adult Primary Care patients?"

The studies will be analysed in relation to the PICO framework (Population, Intervention, Comparison and Outcome) used to develop the original question.

2.3.4(i) Analysis of Study Populations

The papers included in this systematic review were published from 1987 to 2009. The USA and Australia was the setting for the 20th Century studies while a European focus was indicative of later research.

In total the seven studies made up a composite population group of 2416 subjects, with the number of project participants ranging from 66 to 648 per study. In terms of total participant demography, two thirds of all participants were female (n=1602).

This majority split of female subjects was indicative of all included review studies although the magnitude of the ratio varied between individual studies. Both studies in Thompson et al.,[184] only contained female participants.

In terms of subject age, all studies contained adult participants with no subjects under the age of 16 years, as per the original review protocol. The mean age of participants per study ranged from 30 to 58 years, although the method of reporting the mean varied; with one study, Koelwijin-van Loon et al.,[168] reporting only the mean age per randomised group. Both studies contained in Thompson et al.,[184] hinted at an average age of 30 years but no age range was included.

Although all the studies were set in Primary Care, a specific patient group was indicated by five of the seven studies. Two studies, both by Thompson et al.,[184] considered only participants with obstetric or gynaecological problems, while the other three studies focused individually on patients with: cardiovascular problems;[168] unexplained symptoms;[157] and generalised musculoskeletal chronic pain or fibromyalgia.[161]

Although all studies were described as randomised controlled trials, the randomisation group varied between studies. Two of the seven studies, both by Thompson et al.,[184] randomised according to the patient group while the other five studies included in this systematic review, randomised the healthcare provider.

Healthcare provider randomisation was undertaken either individually (n=2) or as a practice (n=3) as indicative of a cluster randomised controlled trial.

The healthcare providers involved in the studies were mainly General Medical Practitioners (n=223) with numbers per study ranging from one to 91. Only one of the seven studies, by Koelwijin-van Loon et al.,[168] looked at healthcare providers other than doctors. In this study 24 practice nurses were recruited as the provider of choice.

In terms of provider demography, only four of the seven studies recorded any details relating to age or gender. Of those recorded, mean age varied from 38 to 45 years, although how this data was reported again varied between studies. Of the 224 providers with details recorded, 170 were male (75.9%) and 54 were female. Almost half of this total number of females (n=24) were practice nurses and were located in only one study by Koelwijin-van Loon et al.[168] The remaining 30 female healthcare providers were General Medical Practitioners making up 15.0 % of the reported 200 doctors. Three of the seven studies included in this review did not report any details relating to their chosen healthcare provider.

In terms of study duration, this varied between the four studies reporting this element; ranging from 12 weeks to one year, with the mode duration being one year. The study characteristics of the seven projects included in this systematic review are summarised in Table 19 and highlight the variation in study data and reported elements.

Table 19: Characteristics of Included Studies

Citation	Country	Study Design	Patient Group	No. Of Subjects	Subject Details	No. & Type Of Providers	Provider Details	Study Duration
Van Bokhoven et al., 2009; Annals of Family Medicine[157]	**Netherlands**	**Cluster Randomised Clinical Trial** **Randomisation of Practices**	Regular patients with unexplained symptoms	Total N=498	Mean Age =43 yrs SD=(16.2) Male= 140 (28%) Female=358 (72%)	Total N=91 General Medical Practitioners	Mean Age=45 yrs SD= (7.3) Male=67 (74%) Female=24 (26%)	12 months
Alamo et al., 2002;Patient Education and Counselling[161]	Spain	**Cluster Randomised Clinical Trial** **Randomisation of Practices**	generalised musculoskeletal chronic pain/fibromyalgia	Total N=110	Mean Age=40.4 yrs SD=(8.5) Male= 3 (2.7%) Female=107 (97.3%)	Total N=20 General Medical Practitioners	No Age Stated No Gender Stated	12 months
Roter et al., 1995;Arch Intern Med [165]	USA	**RCT** **Randomisation of Doctors**	Primary Care Patients	Total N=648	Mean Age=48 yrs Range (16-90yrs) Male=227 (35%) Female=421 (65%)	Total N=69 General Medical Practitioners	Mean Age=40.3 yrs SD= (8.7) Male=63 (91%) Female=6 (9%)	6 months
Koelewijn-van Loon et al., 2009;Preventive Medicine[168]	Netherlands	**Cluster Randomised Clinical Trial** **Randomisation of Practices**	Cardiovascular patients	Total N=589	Mean Age Grp I.=56 yrs SD=(10) Mean Age Grp C=58 yrs SD=(10) Male=264 (45%) Female=325 (55%)	Total N=24 Practice Nurses	Mean Age Grp I=38 yrs SD=(7) Mean Age Grp C=39 yrs SD=(9) Male=0 (0%) Female=24 (100%)	12 weeks
Thompson et al.,1990; Health Psycholog[184] STUDY ONE	USA	**RCT** **Randomisation of Patients**	Obstetric and gynaecological	Total N=66	No Average Age stated Male= 0 (0%) Female=66 (100%)	Total N=1 General Medical Practitioners	No Age Stated No Gender Stated	Not Stated
Thompson et al., 1990;Health Psychology[184] STUDY TWO	USA	**RCT** **Randomisation of Patients**	Obstetric and gynaecological	Total N=105	Average Age =30 yrs Male= 0 (0%) Female= 105(100%)	Total N=2 General Medical Practitioners	No Age Stated No Gender Stated	Not Stated
Evans et al.,1987; British Journal of Medical Psychology[192]	Australia	**RCT** **Randomisation of Doctors**	Primary Care Patients	Total N=400	Mean Age=42.09 yrs Range (17-75yrs) Male=180 (45%) Female=220 (55%)	Total N=40 General Medical Practitioners	Mean Age Grp I= 41.5 yrs Mean Age Grp C=41.8 yrs Male =40 (100%) Female=0 (0%)	Not Stated

Grp I= Intervention Group; Grp C=Control Group

2.3.4(ii) Analysis of Study Interventions and Comparisons

The interventions used in the seven studies included in this systematic review (although having no theoretical stance), aimed to change the effectiveness of the communication interaction during a face to face healthcare consultation. This alteration could be achieved by changing the behaviour of the healthcare provider only, the patient only or both individuals involved in the communication process.

The majority of interventions (n=4) aimed to alter healthcare provider behaviour with some form of communication education programme. This tended to consist of formal teaching and group meetings supported with printed material either in the form of a manual or prompt card. This was often supplemented with role playing sessions where the healthcare provider could practice their newly acquired skills, as in the Roter et al.,[165] study. In some cases, as in the Alamo et al.,[161] study a formal test was undertaken at the end of training to ensure that skills had been adopted. In all studies that used a healthcare provider focused intervention, the provider of choice was the General Medical Practitioner.

Only one study, undertaken by Koelewijn-van-Loon et al.,[168] considered the effect of a communication intervention on both the healthcare provider and patient. Again a communication education programme was used to allow the healthcare providers, in this case practice nurses, to acquire the skills needed to provide effective risk management communication for their cardiovascular patients.

Patients involved in this study were not only given time to digest the facts provided by their practice nurses but were also given a decision support tool allowing them to interact in a more informed way at their next consultation so potentially improving the effectiveness of the communication interaction.

The final two studies, undertaken by Thompson et al.,[184] aimed to change the communication behaviour of the patient only. Both studies used written information handed to the patient in the waiting room before they entered the surgery for their consultation with the doctor. In the first study, patients were given a list of general gynaecological health topics that they could discuss with their doctor and also told to write down at least three questions that they wanted to ask. The second study had two interventions, one where the patients were given a message that indicated their doctor welcomed question asking, and the second where a check-list was given to the patient. In this case patients were asked to try to get the pre-set information highlighted in the check-list from their doctor during the consultation as well as asking their own written questions.

In terms of the number of intervention groups per study, four of the seven studies had only one experimental group; the remaining three studies had two intervention groups which aimed to alter the effectiveness of the communication process. It should be noted however that Van Bokhoven et al.,[157] although having two intervention groups, only used one communication intervention. In most cases the comparison of these interventions was related to usual care (n=5). Although in both studies published in 2009, this was not the case, with the Van Bokhoven et al.,[157] study comparing the intervention against watchful waiting, and the Koelewin-van-Loon et al.,[168] study comparing against nurses taught only in risk assessment.

The application of the intervention during the face to face patient-healthcare provider interaction, varied in format between the seven studies. In the majority of cases (n=5) only one episode of face to face interaction was used, i.e. one consultation or medical visit.

The other two studies (Alamo et al.,[161] and Koelewijn-van-Loon et al.,[168]) recorded more than one visit between the patient and the healthcare provider. In the study undertaken by Alamo et al.,[161] the first face to face visit lasted between 30 to 45 minutes and aimed to establish a patient-centred approach and partnership while the second visit (of similar duration) was used to discuss the results of laboratory and radiological test results. In the Koelewijin-van-Loon et al.,[168] study, practice nurses saw the patients over two 20 minute appointments followed up with a 10 minute telephone call which in some cases was changed to a third face to face meeting.

Although all seven studies aimed to improve the effectiveness of the communication process, only two studies, Alamo et al.,[161] and Roter et al.,[165] formally measured the quality of the interaction. In the Alamo et al.,[161] study, a standardised patient was used and an observer blinded to the experimental allocation of each doctor, rated the interaction quality. This was done using a 13 item questionnaire, the GATHA-RES questionnaire. In the Roter et al.,[165]study, a standardised patient was also used, but in this case an audio-recording of the consultation was taken and analysed using a coding system based on the teaching manual (it is surmised by the author that this coding system is the precursor of the Roter Interactive Analysis System or RIAS). In this study not only are audiotapes of the standardised interaction analysed but also the actual consultations undertaken by the doctors.

Two of the remaining five studies also attempted to evaluate the communication process but in this case a far more simplistic format was used. Both these studies undertaken by Thompson et al.,[184] simply asked patients to count the number of questions they asked during the consultation episode. Thompson[184] did however admit that this means of assessing the communication process was not ideal, preferring to have used a video or audio tape format. Due to ethical disapproval however this could not be used and the more subjective measure of 'number of questions asked' had to be implemented instead. To help alleviate potential bias of patient overestimation in the experimental group, the first Thompson et al.,[184] study also recorded the opinion of the doctor as to the number of questions asked by the patient. It was found that the results of both groups were highly correlated so establishing a means of communication quality assessment. Table 20 summarises the communication intervention element and measures used in each of the seven included research studies.

2.3.4(iii) Analysis of Study Outcome of Interest

The main outcome of interest in this review is that of patient anxiety. In six of the seven studies, this outcome was considered only as a secondary variable although in the project undertaken by Roter et al.,[165] it was the primary outcome of choice. The majority of studies (n=5) focused on patient satisfaction as the main outcome measure, one study however used pain intensity as the primary outcome measure; Alamo et al.,[161] used a visual analogue scale to determine the level of discomfort and pain patients experienced as part of their generalised musculoskeletal condition.

Table 20: Summary of Details relating to Study Interventions

Citation	Intervention Aim	Communication Intervention	No Intervention Groups	Intervention Application	Comparison group	Communication Measure
Van Bokhoven et al., 2009; Annals of Family Medicine[157]	Change GMP communication behaviour	GMP communication education programme to support the decision to postpone ordering patient tests. Involved 2 group meetings and a practice visit.	Two Intervention groups however, only one communication intervention.	One consultation visit.	Watchful waiting for 4 weeks In the comparison group GMPs received no communication training to support test postponement.	None
Alamo et al., 2002;Patient Education and Counselling[161]	Change GMP communication behaviour	GMP communication education programme and a prompt card to ensure patient-centred approach	One intervention group as described.	30-45 min consultation visit with supplemental second visit to discuss test results	Usual care	Communication effectiveness was measured prior to the start of the study using a standardised simulated patient per GMP (GATHA-RES questionnaire was used to assess)
Roter et al., 1995;Arch Intern Med[165]	Change GMP communication behaviour	GMP communication education programme composed of two 4hr sessions including roll playing with simulated case patient. One group only taught emotional handling skills other only taught problem defining skills.	2 communication training intervention groups used: (i) Emotional handling training. (ii) Problem defining skills training.	One medical visit	Usual care	Communication effectiveness was measured using a standardised simulated patient per GMP (97 clinical and psychological items were used to assess the audiotape of this visit) and audio-taping of actual consultations was also used.
Koelewijn-van Loon et al., 2009;Preventive Medicine[168]	Change Patient and Nurse communication behaviour	Nurse communication education programme and patient decision support tool relating to cardiovascular risk.	One intervention group as described.	Two 20 min consultations followed by a 10 min telephone call or face to face consultation	Nurses trained only in risk assessment providing usual care and patients with no decision support tool.	None
Thompson et al., 1990;Health Psychology[184] STUDY ONE	Change Patient communication behaviour	Patient given written advice in waiting room to list their questions that they wish to discuss with the GMP	One intervention group as described	One consultation visit	Usual care	Number of questions asked by patient (as assessed by both doctor and patient)
Thompson et al., 1990;Health Psychology[184] STUDY TWO	Change Patient communication behaviour	Patient given written advice in waiting room. One group was given a checklist of information that they should try to obtain from their GMP (including diagnosis and medication name etc.) while the second group was told to ask questions	2 communication intervention groups used in this study: (i) Patient given a checklist of topics they should ask GMP and asked to write down their questions. (ii) patient told that GMP encouraged question asking. Could not write questions down.	One consultation visit	Usual care	Number of questions asked by patient (as assessed by patient)
Evans et al., 1987;British Journal of Medical Psychology[192]	Change GMP communication behaviour	GMP communication education programme, involving formal teaching, discussion groups and a teaching manual.	One intervention group as described	One consultation visit	Usual care	None

Nevertheless, measurement of anxiety or distress was recorded in some form as part of all seven study outcomes. The scales used to determine the level of anxiety which a patient experienced, varied between papers with two studies (Van Bokhoven et al.,[157] and Koelewijn-van-Loon et al.,[168]) both using a self styled anxiety scale.

In the Van Bokhoven et al.,[157] study a ten point scale was used with patients that scored over the mean value, classified as having anxiety. In the Koelewijn-van-Loon et al.,[168] study a simple two item scale was used. A patient was described as having anxiety if they scored higher than the midpoint of the scale on both the items. The scoring mechanism for this study was not fully explained and the outcome was converted to a dichotomous variable (anxiety present, yes or no) and reported as a simple percentage.

The other studies used validated anxiety measures, with two studies using the GHQ questionnaire (Alamo et al.,[161] and Roter et al.,[165]) although the format of the questionnaire was not described in the Alamo et al.,[161] study. The remaining three studies used the State-Trait Anxiety Inventory.

There were also differences in the patient anxiety measurement points used in each of the seven studies. In the Van Bokhoven et al.,[157] study, pre and post intervention anxiety was recorded by the patient at the same visit. Patients were asked to recall how they felt before they entered the doctor's surgery on the same questionnaire as they recorded post intervention anxiety.

While a discrete pre-intervention anxiety measurement was recorded in three of the seven studies,[161, 165, 168] post intervention measurement frequency varied from only one recording at 12 weeks in Koelewijn-van-Loon et al.,[168] to three post intervention measurements in the Roter et al.,[165] study (at two weeks, three months and six months).

Both the Thompson et al.,[184] studies looked at anxiety during the consultation rather than before and after it while Evans et al.,[192] only measured anxiety after the intervention had taken place.

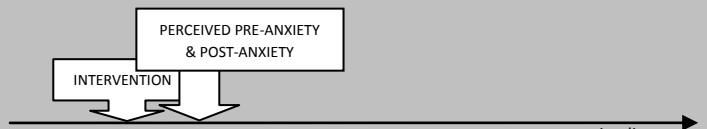
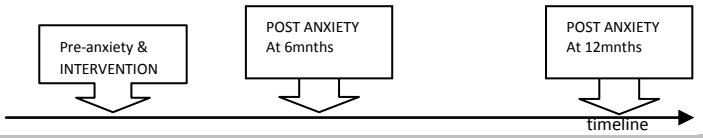
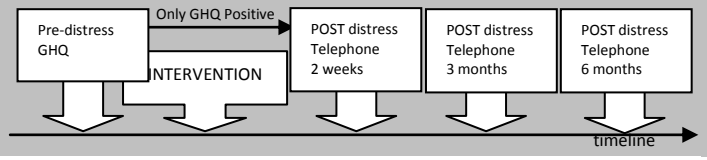
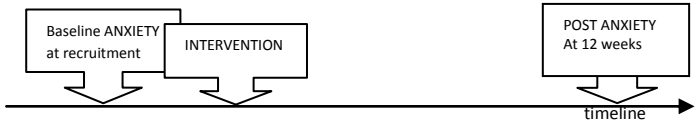
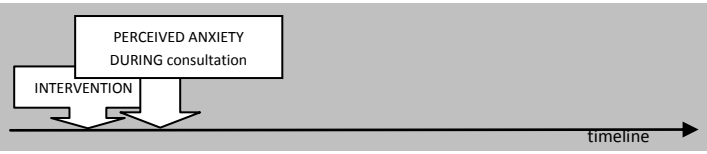
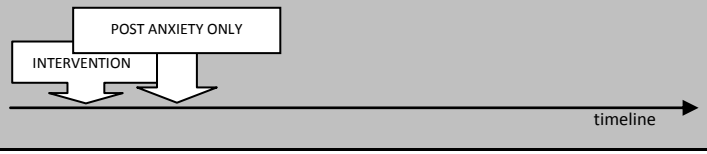
The outcome of the studies also varied. Mean anxiety levels were either compared across the randomised groups at the various time measurement points or actual change in mean anxiety was compared as in the Roter et al.,[165] study. In one study by Koelewijn-Van-Loon et al.,[168] the percentage of individuals with anxiety was compared between the experimental and control groups. While in the Evans et al.,[192] study, Trait anxiety was considered between groups then the State anxiety score considered.

Of the seven studies involved in this review four reported statistically significant changes in anxiety level between the experimental groups and the control group, indicating a 95% probability that the difference did not happen by chance. Table 21 summarises the anxiety outcome details.

2.3.4(iv) Discussion of Results and Study Analysis

Due to the diversity of study outcome measurements and reporting, a meta-analysis which would statistically combine the results of the seven studies was deemed inappropriate.

Table 21: Summary of Details relating to Study Anxiety Outcome Measures

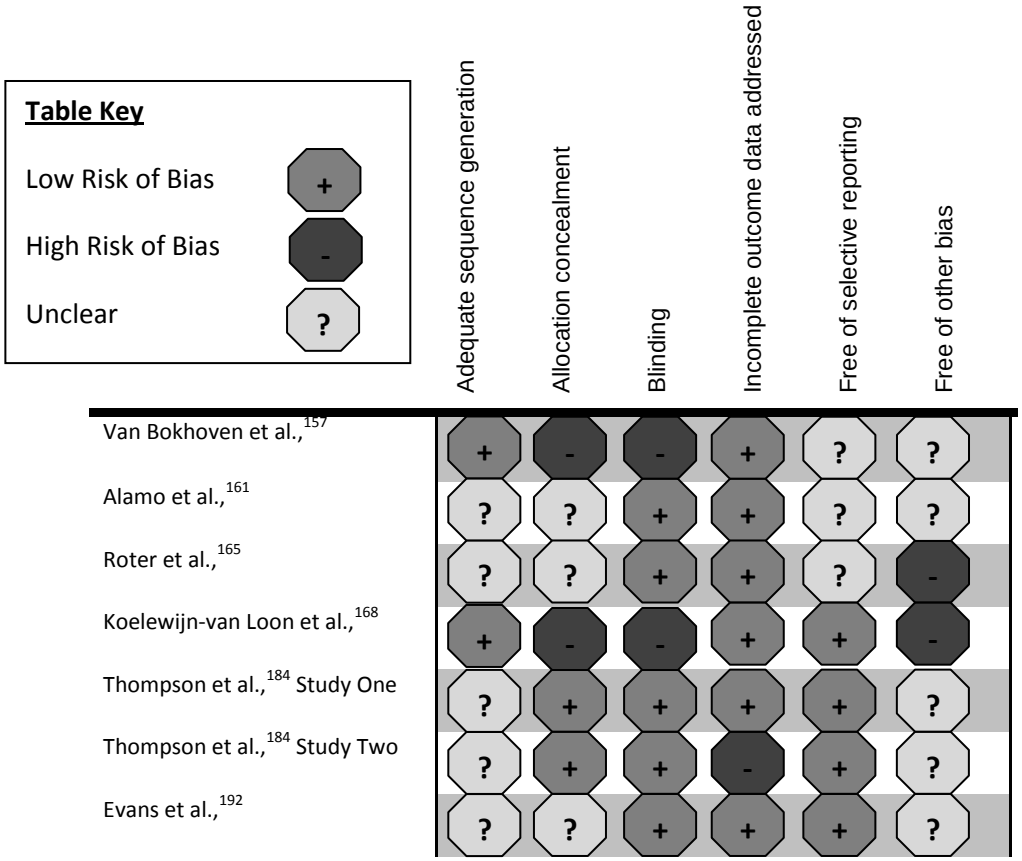
Citation	Anxiety Scale	Anxiety Measurement Points		Anxiety Outcome
Van Bokhoven et al., 2009; Annals of Family Medicine[157]	Self styled 10 point scale		Pre and Post Anxiety measured AT SAME VISIT via questionnaire handed out by GMP, it was completed at HOME and asked to be returned back via post immediately to researcher.	Total anxiety mean post consultation=3.1, SD(2.5) Grp I (test ordering) MEAN=3.1, SD(2.5) Grp I (Communication) MEAN=2.8, SD(2.4) Grp C (watchful waiting) MEAN=3.4, SD(2.7) Difference between groups was not significant
Alamo et al., 2002;Patient Education and Counselling[161]	GHQ-anxiety (Spanish)		Anxiety was measured at baseline when the patient was in the medical surgery. Visits at 6 months and 12 months were also included and an anxiety measure was undertaken.	Change in Mean Anxiety over time Baseline MEAN Grp I=6.2, SD(2.4) Grp C=5.2, SD(2.9) 6 mnths MEAN Grp I=5.4, SD(2.7) Grp C=5.4, SD(2.9) 12 mnths MEAN Grp I=4.6, SD(4.8) Grp C=5.4, SD(2.8) GrpI (Intervention Group) p=0.04
Roter et al., 1995;Arch Intern Med[165]	GHQ-28		Pre-intervention anxiety was measured using the GHQ-28 questionnaire. Only those patients having a positive GHQ score i.e. those with psychological distress, were followed up after the intervention at 2 weeks, 3 months and 6 months.	Change in Mean Anxiety across groups at each time point. 2 wks EH=-6.56 PD=-6.81* Grp C=-5.21 3mths EH=-7.27 PD=-8.63* Grp C=-6.18 6mths EH=-7.74 PD=-8.43* Grp C=-6.41 *significantly different from control
Koelewijn-van Loon et al., 2009;Preventive Medicine[168]	Self-styled 2 item scale		A baseline measurement was taken followed by one 12 weeks later.	Compared anxiety at 12 weeks Grp I (% YES)=39, SD(15) Grp C (% YES)=32, SD(13) It should be noted that significantly more anxious subjects were in Grp C at baseline.
Thompson et al.,1990; Health Psychology[184] STUDY ONE	State-Trait Anxiety Inventory		Patients' anxiety DURING their consultation with the GMP was recorded rather than a pre and post measurement.	Compared anxiety during consultation between 2 groups Grp I MEAN=29.0, SD(9.9) p<0.05 Grp C MEAN=33.5, SD(9.7)
Thompson et al., 1990;Health Psychology[184] STUDY TWO	State-Trait Anxiety Inventory		Patients' anxiety DURING their consultation with the GMP was recorded rather than a pre and post measurement.	Compared anxiety during consultation between 3 groups Grp I (Q) MEAN=30.2, SD(10.6) Grp I (M) MEAN=24.8, SD(8.8) Grp C MEAN=30.6, SD(9.2) No sig Diff.
Evans et al.,1987; British Journal of Medical Psychology[192]	State-Trait Anxiety Inventory		A post-consultation STAI was recorded. No pre-intervention anxiety measure was undertaken.	State compared to Trait anxiety. Grp I TRAIT Mean=48.9, SD(7.5) p<0.001 Grp C TRAIT Mean=45.3, SD(7.6) Grp I STATE MEAN=42.9, SD(7.1) p<0.001 Grp C STATE MEAN=45.3, SD(7.2)

Grp I= Intervention Group; Grp C= Control Group

Although combining results using meta-analysis would improve power and precision, the fundamental differences between the seven studies could create a seriously misleading end result. Therefore the author has chosen a narrative analysis as the means of discussing the key elements in a simple objective format.

The quality of the seven studies included in this review was assessed as part of Proforma Two completion. This was done using the Cochrane Collaboration's Tool for Assessing Risk of Bias.[196] The results of this assessment are highlighted in Figure16 below.

Figure 16: Summary of Study Bias Risk



Study quality varied across the seven projects, with many studies failing to provide adequate information relating to the areas of methodology required to make a definitive analysis. All studies included in this review did, however, reflect a level of self-selection bias which occurs in any project reliant on volunteer subjects.

This issue was formally recognised by Roter et al.,[165] and Koelewijn-van-Loon et al.,[168] but not mentioned in the other studies. Indeed, most study deficiencies which were highlighted simply reflect the real-life challenges of undertaking randomised controlled trials in Primary Care

In terms of results, four of the seven studies highlighted in this review recorded a significant difference in patient anxiety following implementation of the study intervention. The direction of the effect demonstrated a decrease in patient anxiety, consistent over all four significant outcome studies.

Three studies included in this review showed no significant difference in anxiety level between the control and intervention group results (Van Bokhoven et al.,[157] Koelewijn-van-Loon et al.,[168] and Study Two of Thompson et al.,[184]). A self-styled anxiety scale was used in two of these three studies. Only Study Two by Thompson et al.,[184] used a recognised anxiety index, in the form of the State-Trait Anxiety Inventory, with verifiable reliability and validity.

The 10 point scale used in the Van Bokhoven et al.,[157] study used the group's mean anxiety measurement as the cut-off point between those with anxiety and those without.

This issue was further compounded by the lack of recorded pre-anxiety levels, with the only result published, a multivariate logistic regression analysis highlighting the correlation between patients' anxiety before intervention and anxiety after. It should also be noted that the Van Bokhoven et al.,[157] study did not employ discrete pre and post intervention anxiety measures but asked patients to record both at the same time following the intervention.

The study by Koelewijn-van-Loon et al.,[168] used discrete pre and post intervention anxiety measurements but again used a self-styled index based on two questions, with the cut-off point being the midpoint of the scale on both items. Actual scale values and details were not reported but instead the percentage of patients above the anxiety cut-off point was compared to those below.

Results of this study were further muddied by intervention contamination between randomised groups. Some of the practice nurses that had been entered into the control group were so keen to improve quality of care that they received motivational interviewing training to improve their communication effectiveness out with study parameters, so diluting the final study results. Due to these reasons and the questionable validity of the self styled anxiety scales, the reliability of both these studies is somewhat questionable.

Only one study out of the three, Study Two by Thompson et al.,[184] measured the effectiveness of the communication intervention. This was done by simply asking the patient to count the number of questions they asked during their consultation; the more questions asked the more effective the communication process.

Interestingly, the number of questions asked by patients in the Thompson et al.,[184] study was not significantly different between the randomised groups, whereas, in the first Thompson et al.,[184] study (which highlighted a significant patient anxiety reduction), the number of questions asked by the intervention group was significantly greater than in the control group.

In relation to the other four studies, all with significant anxiety outcome results, only Evans et al.,[192] did not report a communication effectiveness measurement.

Both Alamo et al.,[161] and Roter et al.,[165] used formal communication measures and standardised patients to evaluate the effectiveness of the intervention, with the Roter et al.,[165] study highlighting the use of two communication formats.

It should be noted that although the Roter et al.,[165] study used two communication interventions; one focusing on problem defining while the other used emotional handling techniques, only problem defining produced clinically significant results. All studies with significant reductions in patient anxiety level used validated anxiety indexes. In the case of the Alamo et al.,[161] and Roter et al.,[165] studies the GHQ-anxiety questionnaire was used whereas in the Thompson et al.,[184] and Evans et al.,[192] studies the State-Trait Anxiety Inventory was the scale of choice.

All four studies involved interactions between the patient and general medical practitioner, with three of the studies focusing on changing the behaviour of the doctor (Alamo et al.,[161] Roter et al.,[165] and Evans et al.,[192]) and the remaining the communication behaviour of the patient (Study One by Thompson et al.,[184]).

The majority focused on only one episode of face to face communication between the patient and doctor although the Alamo et al.,[161] study used two interaction episodes of similar duration. Only Study One by Thompson et al.,[184] employed the randomisation of patients, the remaining three studies randomised the doctors with Alamo et al.,[161] using a cluster randomised study design. It should be noted that only one general medical practitioner was recruited as part of the first Thompson et al., study.[184]

Study Two by Thompson et al.,[184] used two doctors although there are no reported details regarding these individuals.

In terms of the overall consensus of the studies included in this systematic review, the author has focused on the results of those using a known anxiety index. This is due to the highlighted validity issues of the self-styled anxiety scales. According to four out of the five studies using a validated anxiety measure only the second Thompson et al.,[184] study did not highlight a reduction in patient anxiety, it should however be noted that the same number of questions were asked across randomised groups highlighting a possible issue with communication effectiveness.

In all three studies that used both a valid anxiety measure and a communication effectiveness measure, patient anxiety decreased in the intervention groups. In the Roter et al.,[165] study it was the use of problem defining rather than emotion handling that produced this anxiety decrease. This mirrors the results highlighted in Study One by Thompson et al.,[184] where patients were encouraged to ask their own questions in an attempt to address their presenting complaint.

Interestingly, when Thompson et al.,[184] restricted this question asking in their second study, by introducing a check-list of information that the patient should ask, patient anxiety did not reduce and communication in terms of the number of questions asked was the same across both intervention and control groups.

2.3.4(v) Conclusion

It is the author's opinion, based on the analysis of the results of the studies included in this systematic review that effective communication does decrease patient anxiety and anxiety related health outcomes in adult Primary Care patients. The author recognises that standardised study design in future research would facilitate a more definitive result by allowing a meta-analysis of results.

2.4 Review Conclusion

Effective communication between healthcare professional and patient has been highlighted to be an important factor in both patient outcome and the reduction of patient anxiety levels. Section 2.2, the narrative review, not only demonstrated the integral link between communication and the human body but also the link between interpersonal communication i.e. the patient-health provider dyad, and patient health outcome.

Evidence collated in the narrative review suggested a link between the dyad and reduction in patient anxiety levels. Section 2.3, went on to further investigate this claim by undertaking a rigorous systematic review addressing the question of "Does face to face communication with healthcare providers decrease patient anxiety and anxiety related health outcomes in adult Primary Care patients".

Based on this systematic review, effective communication was shown to decrease anxiety as a patient health outcome. The randomised controlled trials included in this systematic review were however unable to provide contextual evidence relating to why this result occurred.

Evidence considered as part of the narrative review shows that particular verbal and nonverbal elements of the dyadic interaction appear to directly influence patient health outcome. The vast majority of literature within this field mainly relates to the medical encounter, both in Primary and Secondary Care. Studies highlighting communication elements within the patient-dentist dyad, are however limited.

Of those that do consider this interaction, the majority examine the patient-dental specialist relationship. Koerber et al.,[24] investigated the impact of patient race on communication elements in the Orthodontic practice; Sondell et al's.,[25] various investigations focused on the specialist Prosthodontic clinic; while publications by Kulich et al.,[26] considered patient interaction with professionals working in specialist dental phobic clinics. All studies were observational with no intervention element tested, and no patient health outcome recorded.

In an attempt to investigate the 'specialist dentist'-patient interaction, both Koerber et al.,[24] and Sondell et al.,[25] used audio recordings as a means of analysing the dyad, while the Kulich et al.,[26] study pioneered the use of video recordings in the dental surgery setting. Interestingly, Kulich et al.,[26] did not analyse the actual video in an attempt to understand the consultation process, but instead used it to elicit the dentists' perspective of treatment, asking the dentist to comment as the video was shown to them. Despite these and numerous additional articles claiming effective communication as the active ingredient in reduction of dental anxiety, [197, 198] no direct relationship has scientifically been shown.

In 2002, Dailey et al.,[17] demonstrated the use of MDAS within general dental practice, to produce a clinically significant reduction in patient dental state anxiety levels (as measured by STAI-S). The study was undertaken in eight dental practices in North Wales, with one dentist per practice participating. Patients were randomised to either the experimental arm of the study where the MDAS form was handed over to the dentist, or the control arm where the receptionist received the form.

Dailey et al.,[17] reported a reduction in dental state anxiety when MDAS was handed directly from patient to dentist.

This result was also demonstrated by Hull et al.,[18] who further developed Dailey's original study. In this case two Dental Access Centres in the Manchester area were used; each Centre with three recruited dentists. Hull et al.,[18] used a three arm trial to extend the original Dailey et al., study.[17] The study incorporated the original elements of MDAS handover to the dentist and receptionist, but also included MDAS handover to the dentist via the receptionist. In this case, Hull et al.,[18] demonstrated that dental state anxiety reduction only occurred in cases where both dentist and patient had discussed a patient's anxiety status.

Regardless of these promising results however, the actual mechanism by which patient anxiety reduces following MDAS handover is yet unknown. Dailey et al.,[17] in their study discussion, hypothesised possible mechanisms in an attempt to explain this phenomenon; that it could be attenuated by patient expectancy or that MDAS could be used by the dentist as a prompt for more effective communication. The Hull et al.,[18] study, although not a strong effect (like the Dailey et al., study[17]) would suggest that the effect was more associated with communication processes. The group effect in the Hull study was only shown, on more careful inspection, to be associated with patient reports of discussing their anxiety with the dentist. Indeed, when the patient handed over the MDAS form and did not claim to have a 'discussion' about the dental anxiety, then no relative change in state dental anxiety was shown in comparison with the control groups.

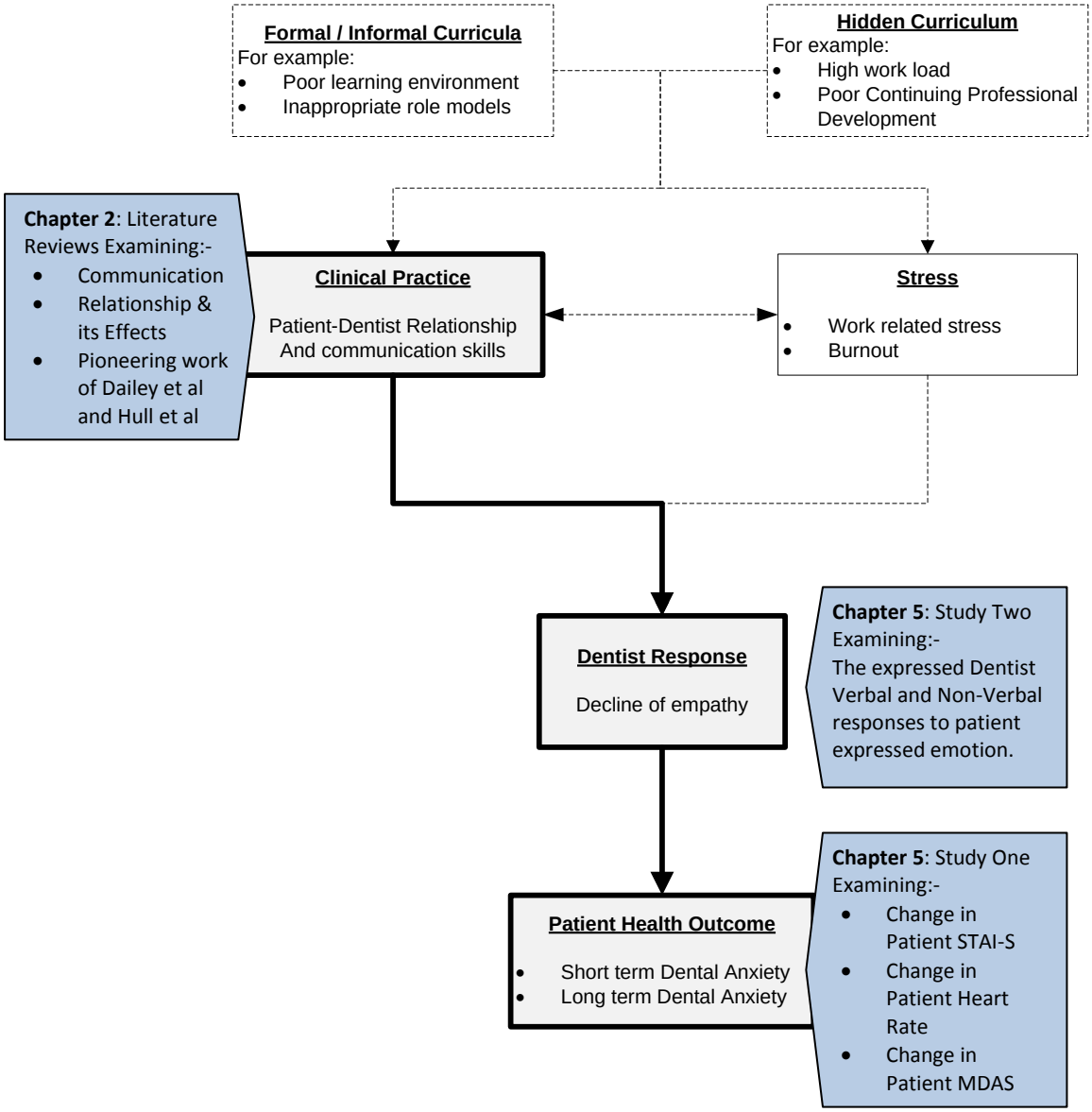
Hence, to date, the hypothesis with a close focus on communication processes is still to be investigated. There is therefore a need within the evidence base to develop studies that will examine, using observational techniques (i.e. video recording) the actual verbal and nonverbal communication (VNVC) elicited as part of the patient-dentist dyad.[17, 18, 21]

It is the aim of this thesis therefore, using the Dailey et al.,[17] and Hull et al.,[18] studies as a foundation, to investigate the (i) effective communication elements in the patient-dentist interaction and (ii) their actual effects on patient dental anxiety; by combining both observational and experimental techniques.

A useful model to explain the structure of this proposed investigation is highlighted in Figure 17. Originally by Neumann et al.,[199] this adapted model details the two main areas proposed for further investigation: (i) the effective elements of the interaction as highlighted on the model by the dentist response and (ii) the actual effect on dental anxiety as highlighted by patient health outcome.

The model is a useful tool in describing how the dentist may react to the patient's expression of dental anxiety during the patient-dentist interaction (as detailed in this Literature Review). By eliciting empathic, effective communication, the dentist may be able to address potential imbalance in the healthcare relationship caused by patient dental anxiety. Identifying and coding these VNVC components, will allow the effectiveness of the dentist's communication to be both quantified and explored qualitatively (Study Two); while the effect of the relationship quality on patient health outcome can also be investigated in relation to both state and trait dental anxiety reduction (Study One).

Figure 17: Model highlighting Structure and Relationship of Proposed Investigations



Adapted from Neumann et al.,[199]

Chapter 3

Aims and Objectives

Chapter contents:-

3.0 Aims and Objectives

3.1 Study Aim

This study aims to explore the elements of verbal and non-verbal communication within the dentist-patient dyad, associated with dental anxiety reduction and formal dental anxiety assessment. For completeness the study Null hypotheses are stated:

(i) In the population of dentally anxious adults attending salaried dental practices in NHS Highland, there is no difference in mean anxiety score (as assessed by STAI-S and Heart Rate) of dentally anxious adults who have given their MDAS questionnaire to the dentist and those who have not.

(ii) In the population of dentally anxious adults attending salaried dental practices in NHS Highland, there is no difference in dental anxiety score (as assessed by MDAS) of dentally anxious adults who have given their MDAS questionnaire to the dentist and those who have not at three month follow-up.

3.2 Study Objectives

Objective One: to determine the long term effect of the patient providing the dentist with their dental anxiety questionnaire (MDAS) on patient dental anxiety.

Objective Two: to explore the expressed VNVC present in the dentist-patient interaction.

Chapter 4

General Methodology

Chapter contents:-

4.0 General Methodology

4.1 Introduction

This chapter provides a general overview of the mixed study methods chosen to investigate the hypothesised association between dental anxiety and Health Communication. The study involves: - an experimental element running in tandem with an observational study, to allow study objectives to be addressed.

As both observational and trial components are intrinsically connected, this chapter provides a generalised approach to methodology prior to individual study presentation and analysis in Chapter 5.

This chapter will therefore provide an overview of mutual elements of both studies and consider: generalised study design; sample size; study setting and participants; interventions; outcomes; randomisation; Ethics and pilot study observations.

All elements included in this chapter have been highlighted by the Consort Agreement 2010, [200] as empirical parts of transparent, quality reporting of randomised controlled trials. These elements will therefore form the backbone to this chapter.

4.2 Study Design

A mixed methods study design was used to address study objectives:

Objective One: - the longer term effect (at three month follow-up) of the patient providing the dentist with MDAS; would be addressed using an extended form of the randomised controlled trial format undertaken by Dailey et al.[17]

Objective Two: - expressed verbal and nonverbal communication (VNVC), present in the patient-dentist dyad; would be investigated using video as an observational format.

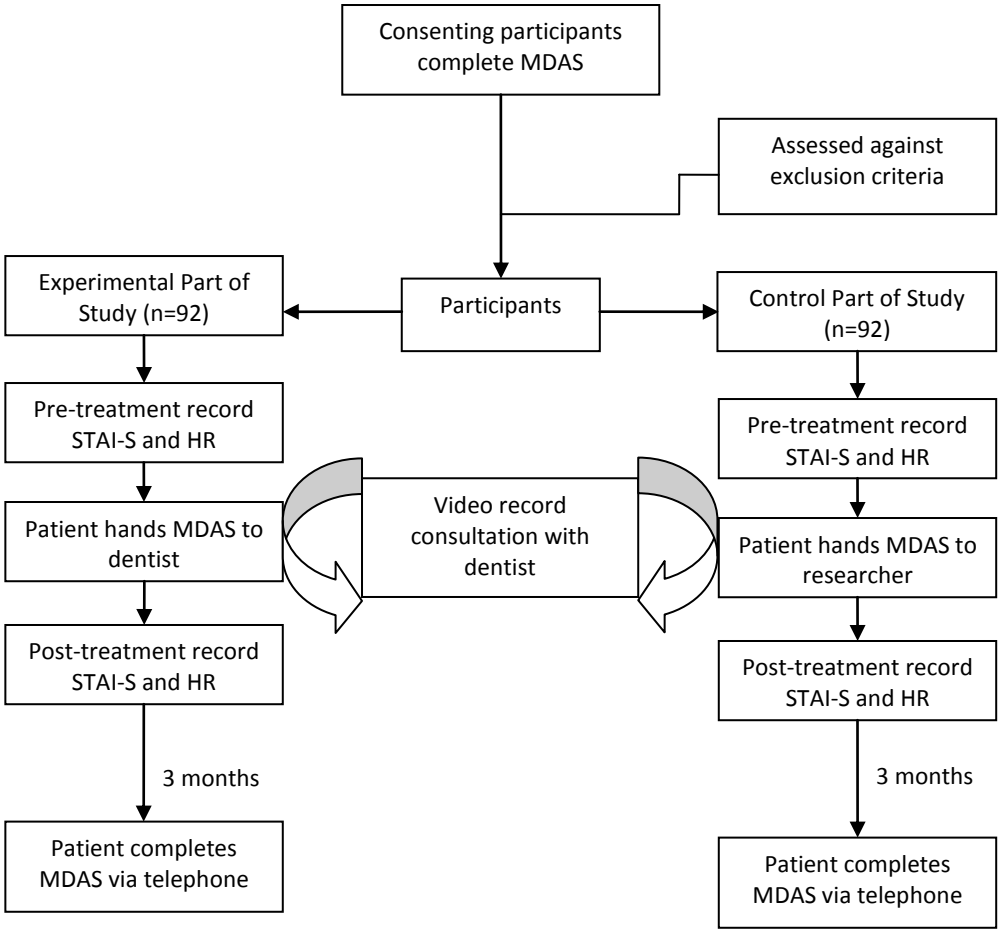
This mixed methods approach was chosen to provide an additional dimension to understanding study outcomes, allowing results of the experimental part of the study to be placed within their clinical context. To do this, the observational part of the study involved video recording each recruited patient's treatment session while they participated in the experimental part of the study.

Originally the proposed experimental study design was a randomised controlled trial (RCT) as undertaken by Dailey et al.,[17] (see Figure 18). Following successful Chief Scientist Office funding [201] (Appendix 6) and peer review, however, the study design was restructured to make it more feasible within the project timescale. This 'imposed' change of study design had major implications not only on how the study was undertaken but also on the number of individuals required to power the trial. The definitive study design (see Figure 19) was composed of:

(1) a randomised cross-over study (replacing the two arm RCT);

(2) and a qualitative and quantitative observational study.

Figure 18: Original Study Design: RCT and Observational Study



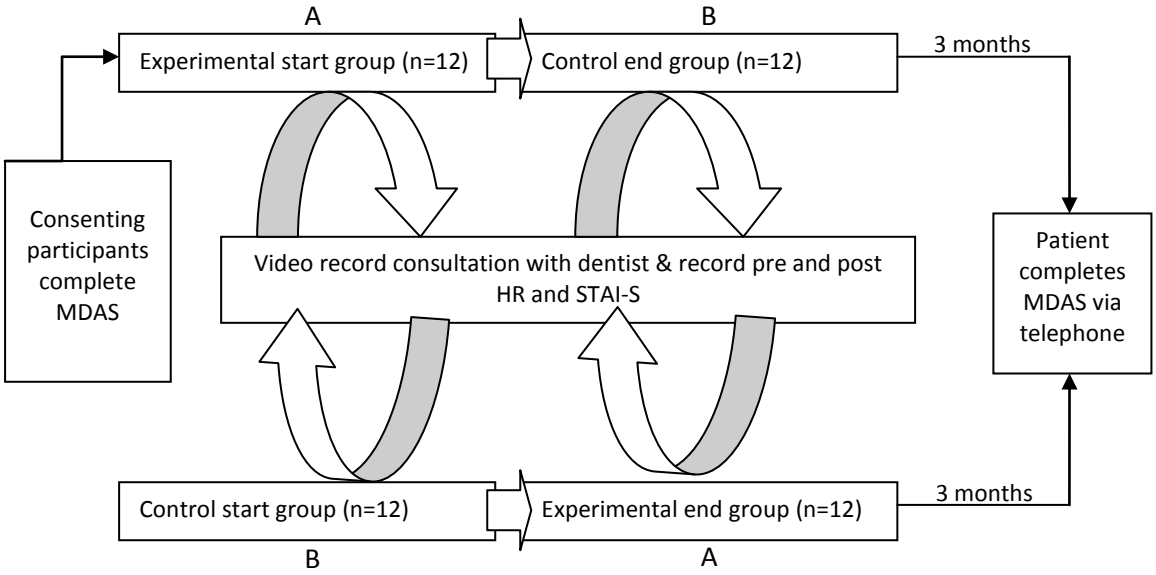
KEY

MDAS Modified Dental Anxiety Questionnaire;
STAI-S Spielberger State-Trait Anxiety Inventory
HR Heart Rate

Experimental Part of Study: completion and handover of MDAS to dentist
Control Part of Study: completion and handover of MDAS to researcher i.e. dentist does not receive MDAS form

Originally a sample size of 92 per group was required based on 80% power to detect a difference in MDAS change score means of 2 assuming a common standard deviation of 4.8 using a 2 group t-test with a 5% two-sided significance level

Figure 19: Definitive Study Design: Randomised Cross-Over and Observational Study



KEY

MDAS Modified Dental Anxiety Questionnaire;
STAI-S Spielberger State-Trait Anxiety Inventory
HR Heart Rate

Experimental Part of Study: completion and handover of MDAS to dentist
Control Part of Study: completion and handover of MDAS to researcher i.e. dentist does not receive MDAS form

In simple terms, a cross-over design involves the allocation of participants to a sequence of both intervention and control elements within a study. Here participants are randomly allocated to either start with the intervention in the experimental group (A) or with the control (B). Such a study is termed an 'AB/BA' design which is the simplest form of cross-over trial.[202]

The use of such a design has a number of advantages and disadvantages in relation to the two arm randomised controlled trial. One of the disadvantages of using such a study design is the potential for carry-over. Carry-over is the effect that occurs when an intervention has a longer lasting influence on a participant than should have been expected. This carry-over effect can muddy trial outcomes particularly within the end control phase of the study and ultimately dilute final results. To overcome this potential problem, some studies incorporate a washout period to allow any longer lasting effects to be removed prior to cross-over. In terms of this study, a period of not less than seven days was deemed appropriate to wash-out the effects of the intervention prior to the cross-over event.

One of the other disadvantages of the cross-over design is related to participant drop-out. In cases where participants fail to complete both control and experimental elements of the study, their sample must be eliminated from the final analysis. In some cases this issue may be significant, resulting in cross-over trials tending to be longer in duration than their parallel randomised controlled trial counterparts.

Despite these challenges however, the main advantage for applying a cross-over design, is in relation to study power.

4.2.1 Sample Size

As participants in cross-over trials act as their own control, inter-participant variation is reduced, which in turn means that fewer participants are required to power the study. This factor is particularly important in relation to this study, where recruitment may be challenging i.e. recruiting dentally anxious patients willing to be videoed in a dental treatment session.

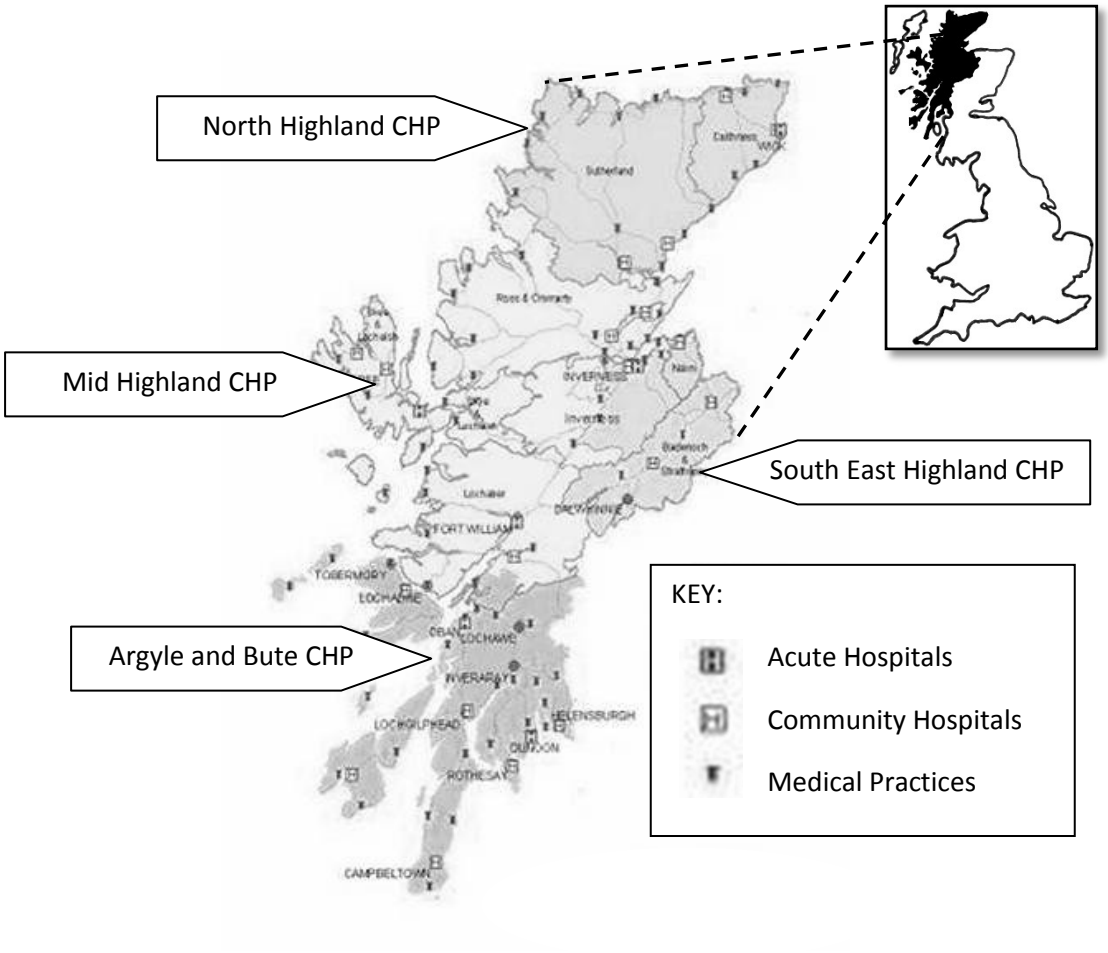
According to the cross-over study power calculation, the sample size of 48 patients in total would be required. This is based on 80% power to detect a difference in Modified Dental Anxiety Scale (MDAS) change score means of 2.00 assuming a common standard deviation of 4.8 using a two group t-test with a 5% two-sided significance level.

4.3 Study Setting

This mixed methods study was set in NHS Highland, the most northern of the UK's mainland NHS Boards (see Figure 20). NHS Highland has a 32,512 sq/km^2 catchment area equating to around 41% of the Scottish land mass, [203] and includes some of the most sparsely populated areas in the UK. It is made up of four Community Health Partnerships (CHPs): North Highland CHP, Mid Highland CHP, Argyle and Bute CHP and South East Highland CHP, with each CHP servicing a total Highland population of 310,000 residents.

CHPs were established in Scotland following the National Health Service Reform (Scotland) Act of 2004.[204] This Act called for the incorporation of CHPs into the NHS structure to manage healthcare delivery in a new community-led way.

Figure 20: NHS Highland and Component Community Health Partnerships (CHPs)



Key players from NHS Primary and Secondary Care, social services and the community were encouraged to come together and organise the provision of integrated care, tailored directly to the needs of their individual community.[205]

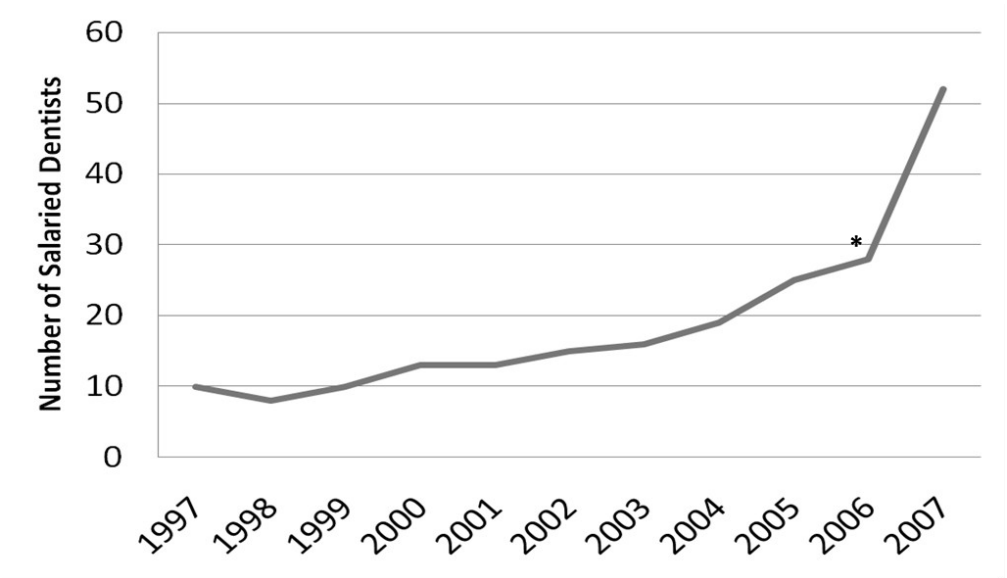
Around forty CHPs are present throughout Scotland with all NHS healthcare services (Primary and Secondary Care) divided according to their designated CHP area. This includes NHS Salaried Dental Services (SDS).

4.4 Study Participants

4.4.1 Participants: Dentists

The SDS is currently the dominate provider of NHS dental care services in the Highlands.[206] The service has evolved over recent years in response to growing NHS dental access problems, which have historically stemmed from servicing such a remote and rural area. Figure 21 highlights the growth of Highland's SDS over the last 10 years. It should be noted that in 2006 the Argyle and Bute region became part of NHS Highland.

Figure 21: Growth of Salaried Dental Service in NHS Highland



***Following years include Argyle and Bute**

The reason for setting the investigation in the Highland area stems from the issue highlighted by the Narrative Review in Chapter 2 (see page 36). Although both the Dailey et al.,[17] and Hull et al.,[18] studies demonstrated a reduction in dental state anxiety following MDAS handover, it should be noted that recruited dentists were not only instructed in the use of MDAS prior to study commencement, but were also situated in an area of the UK where MDAS had not only been promoted but also taught at dental undergraduate and postgraduate levels.[207]

It could therefore be argued that the connection between MDAS use and effective communication may have already been imprinted on study dentists, so influencing their behaviour when they received the MDAS form. To avoid such bias being introduced into the current investigation, an area where MDAS was not part of routine care, and had not been taught at undergraduate and postgraduate level was essential. NHS Highland was therefore chosen.

To recruit SDS dentists in NHS Highland, an initial presentation entitled “Effective Communication in Primary Dental Care” (see Appendix 7) was undertaken at dental clinical discussion groups in each CHP, excluding Argyle and Bute where key dentists had already seen an initial presentation to the NHS Highland Salaried Dental Executive Board. It should be noted that during this initial presentation, MDAS use was not highlighted.

The presentations were undertaken to encourage dentist recruitment from across NHS Highland. Six dentists were required in total, although the study called for the co-operation of the entire dental team: dentist, dental nurse and receptionist.

4.4.2 Participants: Patients

Only patients attending recruited SDS Primary Care Clinics could potentially be asked to participate in the study. Actual patient participation was dependant on adherence with the following inclusion and exclusion criteria (see Table 22).

Table 22: Patient Inclusion and Exclusion Criteria

	Inclusion Criteria	Exclusion Criteria
1.	Agreed to participate in study	Declined invitation to participate
2.	Able to give written informed consent	Unable to give informed consent e.g. due to mental capacity or language barriers
3.	Aged 18 years or over	Under 18 years old
4.	Generally fit and well	Ill health, pregnancy, psychiatric illness, heart medication
5.	Treatment session	Treatment with sedation or hypnosis
6.	MDAS scoring 19 and over or 5 on any one question	MDAS scoring less than 19 or not scoring 5 on any one question

Patients had to be able to provide written informed consent to participate in the study (see Appendix 8 for patient consent form). Individuals, who were unable to consent for themselves due to age, mental capacity or language barriers, were excluded as were those who declined to take part in the study.

As the study involved the measurement of emotional and physiological manifestations of dental anxiety, patients with any medical condition having the potential to interfere with these variables, were rejected. This was also the case where dental treatment procedures involved altered patient mental states, e.g. hypnosis and dental sedation.

In other words, suitable patients included those attending the recruited dentist, able to provide written informed consent, being aged 18 years or over and in good general health.

Such patients were invited to take part in the study if on the day of their dental treatment appointment, they scored 19 or more in total, or five in any one question according to their MDAS score. This ensured that the study focused on only those patients within the more extreme regions of the dental anxiety continuum.[124]

Indeed, the cut-off score of 19 had already been confirmed within the literature as a suitable score for identifying highly dentally anxious individuals.[208] In addition, by considering patients who scored the maximum of five in any one question but perhaps did not score 19 or more in total, patients who were acutely anxious over one particular aspect of dental treatment (e.g. local anaesthetic injection) but not other procedures, could also be included.

This approach to targeting dentally anxious patients was employed in the studies by both Dailey et al.,[17] and Hull et al.[18]

4.5 Intervention

The communication intervention used in this study was the handing over of the completed MDAS form, from the patient directly to the dentist. This intervention was previously used in both the Dailey et al.,[17] and Hull et al.,[18] studies.

In this case however, unlike the earlier studies, the actual transfer of the form could be viewed by the researcher (JH) via a video recording. Here the video highlighted the presence of any patient and dentist 'discussion' related to the content of the MDAS form.

It should be remembered that MDAS (see Appendix 9) is essentially a self-assessment instrument, completed by the patient and used to measure dental trait anxiety levels. It is composed of five self-evaluating statements (not anxious=1, slightly anxious=2, fairly anxious=3, very anxious=4, extremely anxious=5) in relation to five dental scenarios (attending for treatment tomorrow, sitting in the waiting room, having a tooth drilled, having a scale and polish, and having a local anaesthetic injection). The maximum MDAS score for any one question is five (equating to the 'extremely anxious' statement), while the maximum score for the entire inventory is 25.

MDAS, essentially measures the underlying patient dental trait anxiety associated with each of the five dental scenarios, providing the dentist with a profile of their patient's dental anxiety.

Only those patients in the experimental group were required to hand their completed MDAS form to the dentist. Those patients allocated to the control group were instead instructed to hand their completed MDAS back to the researcher.

4.6 Outcome Measures

4.6.1 Primary Outcome Measure: MDAS

The primary outcome measure used in this study to quantify patient dental trait anxiety was MDAS score; a measure already shown to be reliable and valid;[209] with no instrumentation effect.[210]

MDAS was completed in this study as part of the patient recruitment process, with those scoring 19 or more or five in any one question, eligible to take part. The score from this pre-treatment MDAS assessment would then provide the study's baseline data, with recruited patients being contacted by telephone three months later to complete a second post-treatment MDAS form.

4.6.2 Secondary Outcome Measures

(i) Heart Rate

To provide a measure of the physiological manifestation of dental state anxiety, Heart Rate would be recorded. A simple finger pulse-oximeter (MD300-D Finger Pulse Oximeter) would be used immediately prior to and following the patient's dental treatment appointment. Heart Rate would be recorded over a period of one minute to allow stabilisation of the reading.

(ii) Spielberger State-Trait Anxiety Inventory (STAI-S)

To quantify patient emotional dental state anxiety change, as in the original Dailey et al.,[17] study (and the study by Hull et al.,[18]), this study used the Spielberger State-Trait Anxiety Inventory (STAI-S).

This inventory is a validated self-assessment form with high reliability, composed of six items each with corresponding statements and scores of 1 to 4; ranging in level of intensity from 'not at all' to 'very much so'. (The STA-S form is included in Appendix 10).

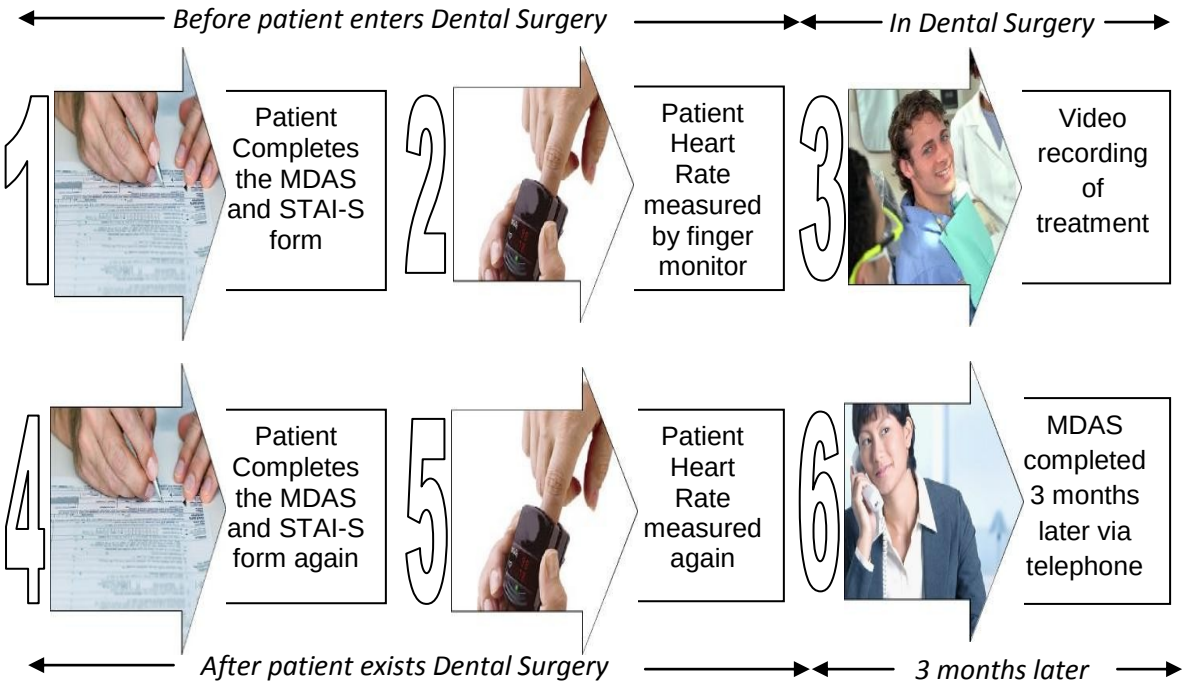
All recruited patients were required to complete the STAI-S questionnaire immediately before and after their dental treatment.

4.6.3 Observational Study Outcome Measures

All patients participating in the study would also have their dental treatment appointment videoed to provide a contextual element to the study. This was done using a small webcam (Logitech QuickCam Vision Pro 9000) linked to a Laptop computer (closed system). All recorded video clips would then be stored on an encrypted hard-drive (Maxtor One Touch 4 Plus).

Observer XT software (version 8) was used to allow direct video coding and analysis with two separate coding systems; the Verona Coding System (Verona CoDES)[211, 212] and an author generated behavioural coding system detailed in Chapter 5. The analysis of the video recordings provided both quantitative and qualitative outcomes. The sequence of Outcome measures (Primary, Secondary and Observational) undertaken during the patient appointment are highlighted in Figure 22.

Figure 22: Sequence of Outcome Measurements during the Patient Appointment



4.7 Randomisation

Due to the study design, patients could only be recruited on the day of their treatment appointment. For this reason and due to the nature of patients with dental anxiety, it was unrealistic to expect patients to take part in both the control and experimental parts of the study. Patients were therefore only asked to participate in the study once. This had implications with regard to the randomisation process.

In other words, the randomisation used in this cross-over study had to be focused on the dentists rather than the patients, with dentists being randomised to either start with the patient intervention or control group.

The randomisation was undertaken prior to the start of the study by an independent statistician (KC, at DHSRU) who provided a computer generated randomisation list. This list was used to allocate dentists to their designated start group.

To overcome some of the limitations of the Dailey et al.,[17] and Hull et al.,[18] RCT studies, where the blinding of dentists to the intervention was questionable (i.e. practitioners in both studies were well schooled in MDAS use even prior to study commencement) and the need to avoid possible cross contamination between the cross-over study start groups, it was essential that the unit of allocation was the clinic rather than the individual dentist.

4.8 Study Blinding

All participants in the study were blinded to the study design as well as their randomised allocation. Dentists were aware of the communication element of the project, following the initial presentation on 'Effective Communication in Dental Primary Care' and on initiation of the project were aware of the focus on dentally anxious patients.

Both patients and dentists could not be blinded to the use of the video camera due to both ethical and technical factors but were blinded to the actual study intervention, the MDAS handover.

Dentists were not given any instruction or information relating to the use of MDAS and were unaware of its significance in relation to the study design.

4.9 Ethics

This study sought ethical approval from the North of Scotland Research Ethics Committees (REC reference number: 08/S802/70). Approval was granted on the 7th May 2008, on the condition of management approval at NHS Highland sites (i.e. R&D approval). R&D approval was granted to this project on 22nd August 2008 (see Appendix 11)

It should be noted that a substantial amendment was also submitted by the author on the 27th July 2009, following challenges in patient recruitment. The amendment highlighted also in Appendix 11, was however rejected on the 18th August 2009.

4.10 The Pilot Study

To understand the implications of running this study within NHS Highland's SDS, a pilot study within Argyle and Bute CHP was undertaken by the author (see Figure 15).

A practice in Rothesay, the only large town on the Isle of Bute, had already expressed an interest in the study and was keen to participate. The practice consisted of three dentists running a two surgery clinic, servicing an island population of 7,228 inhabitants.

As the Practice Principal already had a keen interest in the patient-dentist interaction (having used videos as part of practice quality improvement) and as the Practice manageress had a background in Psychology, this practice could not be used as one of the actual study participants.

Instead, the Rothesay practice was invited to participate in a three day Pilot study focusing on the practicalities of running the study in NHS Highland.

Practice Staff were encouraged to comment and provide input with regard to any problem areas, particularly in relation to facilitating the study within a busy NHS Clinic.

4.10.1 Pilot Study Results

The pilot study was undertaken on the 11th, 12th and 13th of March 2009 and had the co-operation of the entire dental practice, including all three dentists - the Practice Principal, the Practice Associate and the Vocational Trainee. This provided a good range of dental experience and hence a wide range of relevant input.

The pilot study was run as close as possible to the way the definitive study would be undertaken, however due to low MDAS results, the author had to use patients who claimed to be anxious yet did not score 19 and over or five in any one question on the MDAS form. All videos were erased following the pilot study.

The following issues were highlighted by both practice staff and the author as requiring more development prior to definitive study roll-out.

1. **Patient Confidentiality Issues**

   One of the main issues raised in the pilot study was the need for a separate room for confidential discussion with the patient, and to undertake outcome recordings. If additional space was not available then the only alternative was to screen off an area of the waiting room.

The pilot study dental team felt that this would be an inappropriate alternative. A dedicated room would therefore have to be sought at each definitive study site.

2. Timing Issues

Another issue highlighted by the pilot study was that of time. The time taken to consent and complete the initial outcome measures had a knock-on effect to the dentists' schedule, with each participating patient, making the dentist later for the next. A time buffer therefore had to be added to patients' appointments, asking them to attend 10 minutes before their treatment was due.

3. Information Flow Issues

Two of the three dentists relied on the dental nurse to collect the patients from the waiting room while the third dentist collected the patients personally. In this case, patients would have already started to converse with the dentist before they entered the dental surgery which would have implications relating to the capture of the first minutes of the patient-dentist dyad on film.

The pilot study also highlighted an issue with regard to how the form was transferred to the dentist. Initially during the pilot study, the dental receptionist collected all the forms completed by the patient and then took them through prior to the patient entering the surgery.

A way of altering this information flow had to be developed to allow direct patient handover of the MDAS form.

The author therefore, volunteered to get the patient from the waiting room for each dentist, so ensuring patients had their MDAS form with them prior to surgery entry.

4. **Equipment Issues**

Video camera placement was also highlighted as a potentially problematic area. The camera had to be placed in an area which would capture the first moments of the interaction, yet not interfere with general workflow.

To do this the camera angle had to include the surgery doorway as well as the dental chair. For some surgeries this was challenging as the video tripod posed an obstacle for both patients and dentist.

Moving the camera onto a work surface, or ideally above the work surface (e.g. on top of a unit) provided a solution to this problem.

Sound capture also proved to be better when the camera was above the work surface, hence limiting interference from radios and dental equipment.

Actual camera placement required the agreement of not only the dentist but also the dental nurse. Indeed, the pilot dental nurses were instrumental in establishing the best areas for camera placement.

4.10.2 Pilot Study Conclusions

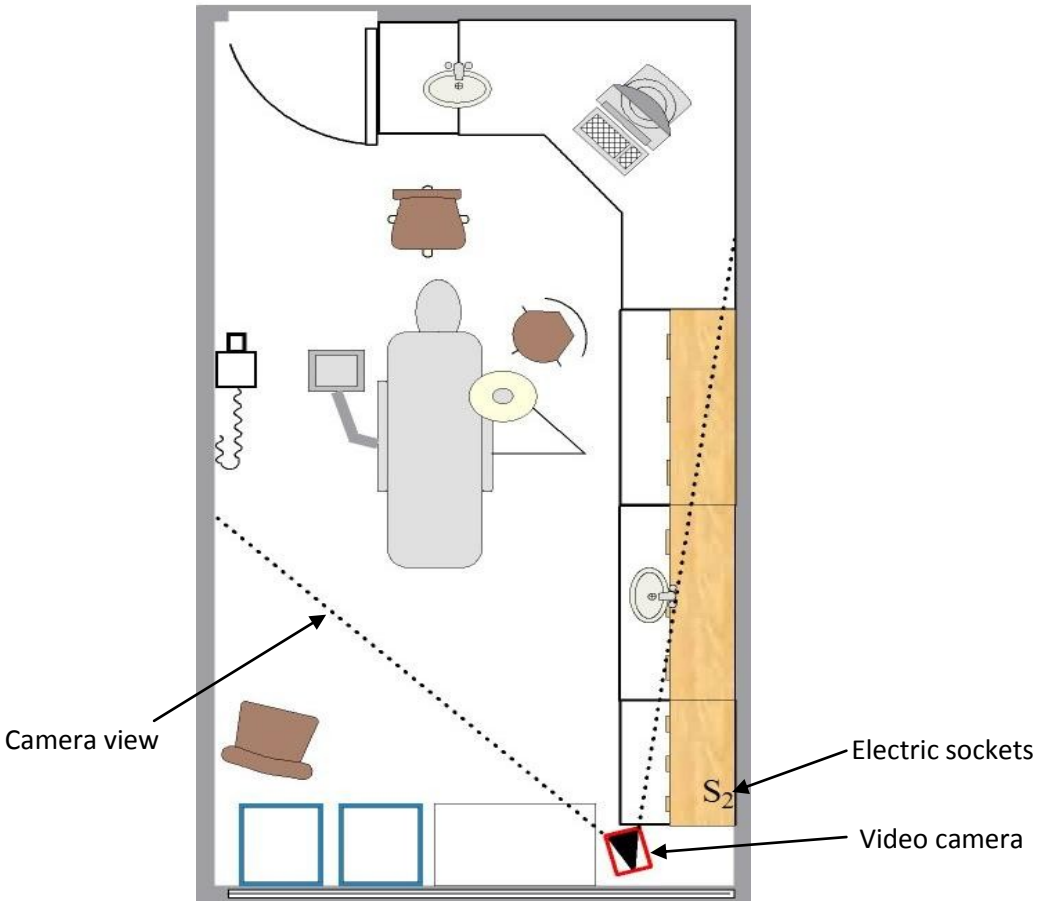
The pilot study raised a number of key issues that needed to be addressed by the author prior to roll-out of the definitive cross-over study.

To do this the author visited each potential study practice, not only to discuss the feasibility of the study but also to meet with key practice staff.

Following dental staff consultation, potential study surgeries were examined and individual plans drawn, highlighting the most appropriate location for camera placement (see Figure 23). This ensured total agreement of both dentist and dental team prior to study commencement.

Practices where no additional confidential space could be provided, for the initial meeting of patients to establish informed consent and undertake outcome measurements, were eliminated from the study.

Figure 23: Example of Surgery Plan Developed to Establish Camera Placement



4.11 General Methodology Conclusion

In conclusion, this chapter provides a general overview of the methodology used by the author to investigate the hypothesised association between dental anxiety and Health Communication.

The chapter provides details on the development of the study design; design advantages and disadvantages; the power calculation; the choice of study setting; as well as the designated NHS Highland population group.

By laying out these elements along with details regarding study intervention, outcome measures and randomisation process, the author aims to provide a clear and decisive overview as to how this mixed methods study was undertaken.

A summary of key study methodology elements is highlighted in Table 23.

Table 23: Summary of Study Elements

	Study Element summary
Study Design	Mixed Methods Study: • Randomised Cross-over study (quantitative) • Observational study (quantitative and qualitative)
Population	Primary Dental Care: NHS Salaried Dental Services
Intervention	Handover of MDAS form directly to dentist from patient
Comparison	No MDAS form taken through to dentist by patient
Outcome	Health Outcomes • Dental state anxiety • Dental trait anxiety Primary Outcome: MDAS score Secondary Outcomes: Heart Rate, STAI-S measurement. Observational Outcome: Behavioural and Affective outcomes.

Additional modifications to actual study facilitation stemmed from the pilot study results.

The pilot study was instrumental in ironing out potential problem areas which could have jeopardised the integrity of the definitive study. These modifications were incorporated prior to study roll-out.

In summary, this section has detailed the mutual elements of both randomised cross-over trial and observational study. The following chapter, Chapter 5 will now address elements relating exclusively to each study in terms of methodology, results and analysis.

Chapter 5

The Studies and Results

Chapter contents:-

5.1. Introduction to Studies & Results

5.1.1. Introduction

This chapter highlights the analysis and results of two studies conducted as a means of investigating the hypothesised link between effective communication and dental anxiety. Both studies run in parallel and therefore have an intrinsically connected methodology as highlighted in Chapter 4.

In this chapter the two studies will be considered individually. For ease of reading, the chapter will be divided into three main sections: Section 5.1 will provide the general introduction to the chapter and detail mutual outcome elements as well as the overall baseline data; Section 5.2 will detail the first study, the randomised cross-over trial used to address Objective 1; while Section 5.3 will consider the trial's parallel observational element which will address Objective 2.

A mixed method study design was employed by the author in order to highlight the significance of contextualising scientific results to answer, not only the question of whether an intervention works, but also to investigate why.

The studies reported in this chapter were conducted by the author within NHS Highland's Salaried Dental Services (SDS) from May 2009 to May 2010.

5.1.2. Participant Flow (Losses & Exclusions)

One of the mutual elements of both the randomised cross-over and observational studies was participant flow, defined as the total number of patients at various stages of this mixed methods study.

The participant flow details the number of patients who actually completed the study in its entirety, as well as those who did not. Those that did not complete were either excluded at the initial recruitment stage or lost to follow-up (study attrition). Figure 24 details the overall participant flow of this mixed-methods design.

A total of 1096 patient information leaflets (as highlighted in Appendix 12) were posted or handed to individuals attending the six dental practices involved in the study. Patients were initially contacted, either personally by a member of the dental team or by post, the week before their dental treatment appointment. Only those patients who fitted the initial inclusion criteria were contacted.

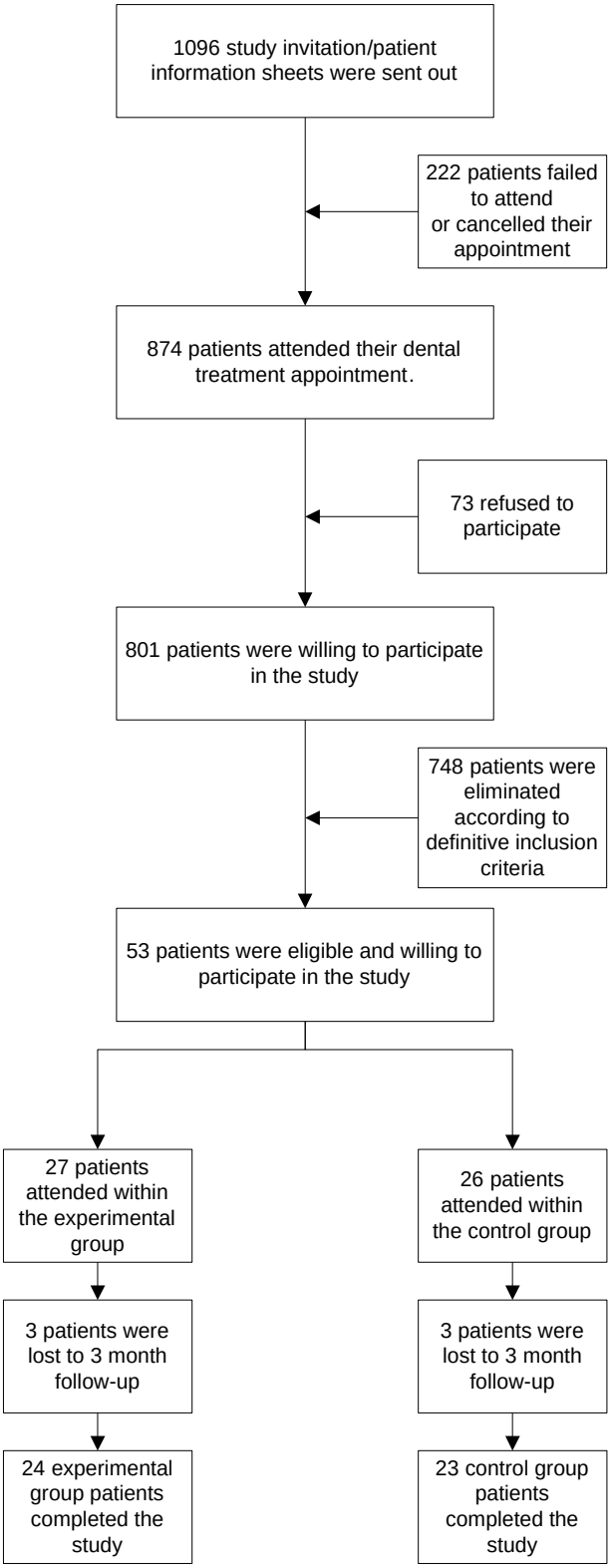
To be eligible for invitation, patients had to be:

- Aged 18 years or over
- Generally fit and well
- Able to provide written informed consent
- Treated without sedation or hypnosis
- Attending for dental treatment (preferably as a first appointment).

Due to the Ethical obligations of this study, information sheets had to be provided to the patient at least 24 hours prior to their appointment. This meant that most emergency dental appointments had to be excluded.

Of the 1096 potential patients contacted, only 874 kept their appointment, with 222 patients either failing to attend or cancelling at the last minute. A further 73 patients refused to take part in the study, while 748 patients were excluded following implementation of the definitive exclusion criteria which included the need to score 19 or over i.e. extremely anxious on MDAS. MDAS score was the main limiting factor.

Figure 24: Mixed-Methods Study Participant Flow



A total of 53 patients were deemed to fit the entire inclusion criteria. Only the author was aware of the MDAS score element where patients had to score 19 or over, or five in any one question.

Of all the patients that agreed to take part, 49 completed both pre and post treatment measurements; while four were too upset to return to the researcher following their dental treatment (as shown by the patients exiting the surgery immediately after treatment).

Of those who had both pre and post treatment measurements, five experienced technical problems with their video recording. On one occasion the dental nurse switched the video camera off by mistake so recording only the initial half of the session, while on another occasion a cupboard door was opened in front of the camera masking the patient during the treatment phase of the appointment. In the remaining three occasions, the camera did not record any sound.

All patients who consented to take part in the study were contacted by telephone for a three month follow-up MDAS assessment. Of the 53 participating patients, six were lost at follow-up. This left a remaining total of 47 patients who completed the study.

5.1.3. Study Recruitment

5.1.3.(i) Dentist Recruitment

In terms of dentist recruitment, once R&D approval from NHS Highland had been granted in late August 2008, the author was given permission to approach dental teams in Highland.

This recruitment process began by first introducing the proposed study at a meeting of the NHS Highland Salaried Dental Executive Board. A talk on 'Effective Communication in Dental Primary Care' was provided to key dental staff within the area. Following this initial presentation the Rothesay practice was recruited as an initial pilot study site.

The presentation was also undertaken at the remaining CHPs in NHS Highland at each Dental Clinical Discussion Group.

Following this initial round of dentist presentations, two salaried dentists volunteered to take part in the study. The remaining four dentists were finally recruited in 2009 just prior to the pilot study. Following the pilot study the author visited each dental practice to:

1. Ensure a dedicated room could be provided to allow for patient consultation and outcome measures.
2. Meet with key practice staff to agree camera placement.
3. Consent dentists into the study (dentist consent form highlighted in Appendix 13).
4. Supply the dental teams with study introduction packs; which contained patient information leaflets, a poster to be displayed in the surgery waiting room (Appendix 14) and a quick reference guide to the selection of patients suitable for the study (Appendix 15).
5. Demonstrate equipment and discuss current patient flow.

In cases where clinics did not have the designated confidential space for outcome measurement, or were situated too far away to be able to run the project efficiently, clinics were excluded from participating in the study.

Issues regarding members of the dental team who were unhappy about appearing on the videos were addressed by developing special consent forms for dental nurses (see Appendix 16), stating that any appearance would be 'blanked'. This implementation allowed for full participation of the entire dental team.

A time table of weekly visits was organised for each clinic and the video equipment moved between surgeries.

5.1.3(ii) Patient Recruitment

Following the pilot study in March 2009, the project was undertaken to Highland and patient recruitment commenced data in May 2009 till May 2009.

Practices were asked to place a poster highlighting the research project in their patient waiting rooms weeks prior to project commencement. Patient information leaflets were distributed either by hand or by post to those due to attend for dental treatment.

As part of the Ethical obligation, patients were required to receive study information at least 24 hours prior to the day of their treatment appointment. Patients were then asked again whether or not they wished to take part on the day of their appointment.

5.1.3(iii) Recruitment and Retention Issues: Dentists & Patients

In the initial stages of the study, dentist recruitment was slow. Many dentists were concerned that the study may cause time implications on already tight schedules, while practice staff were uneasy about the video element to the study. It should be noted, that unlike medical practice where doctors and their teams have been using video as a form of assessment as well as peer review for many years, [213] it is a new and rather challenging concept for Dental Primary Care.

In some cases the actual practice layout caused the challenge, providing no additional confidential area for patient outcome measures. Despite these challenges six suitable dental practices were recruited.

In terms of dentist retention, one practice dropped out due to the dentist emigrating. No other dentists within the practice were prepared to take part in the study therefore it was replaced with an additional practice. Due to the study's cross-over design all related data became obsolete.

In terms of patient recruitment, again this was challenging. Patients could only complete the MDAS form on the day of their dental treatment appointment therefore full compliance with the inclusion criteria was not known until that patient attended. Many patients, although happy to take part in the project, were not of a high enough dental anxiety level to be accepted into the study. The low recruitment rate resulted in the researcher submitting a substantial amendment to the Ethics Committee on the 27th July 2009 as previously highlighted in Appendix 11. This amendment was, however, rejected on the 18th August 2009, due to the Committee's concerns that patients may not have 24hours to consider whether they wished to participate in the study or not

External project factors also affected patient recruitment. Mid-way through the recruitment phase (January 2010) a BBC news report highlighting a breach in patient confidentiality at the Southern General Hospital, in Glasgow (i.e. photographs of patient operations being posted on Face Book), made many patients suspicious of consenting to have their treatment appointment videoed.

In an attempt to increase patient numbers, other dentists within each practice were encouraged to participate in the study. Only in one practice was this successful with an additional dentist being consented and able to recruit patients.

5.1.4. Baseline Data

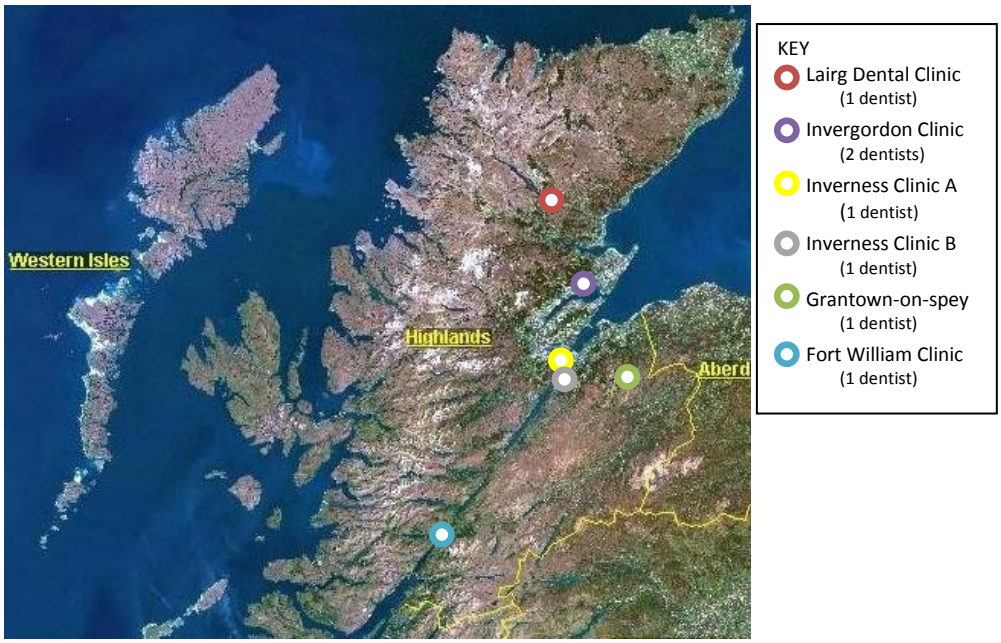
To effectively describe both the patient and practitioner groups who participated in this study, data relating to demographics for patients and dentists as well as patient clinical characteristics were analysed.

5.1.4(i) Demographic Profile: Dentists

A total of seven dentists (six female and one male) were involved in this study. The dentists' year of graduation ranged from 1981 to 2009; with the mean number of years since graduation being 15.5 (SD 11.78).

In total six Salaried Dental Clinics participated in this study. The location of each is highlighted in Figure 25.

Figure 25: Location of Dental Clinics



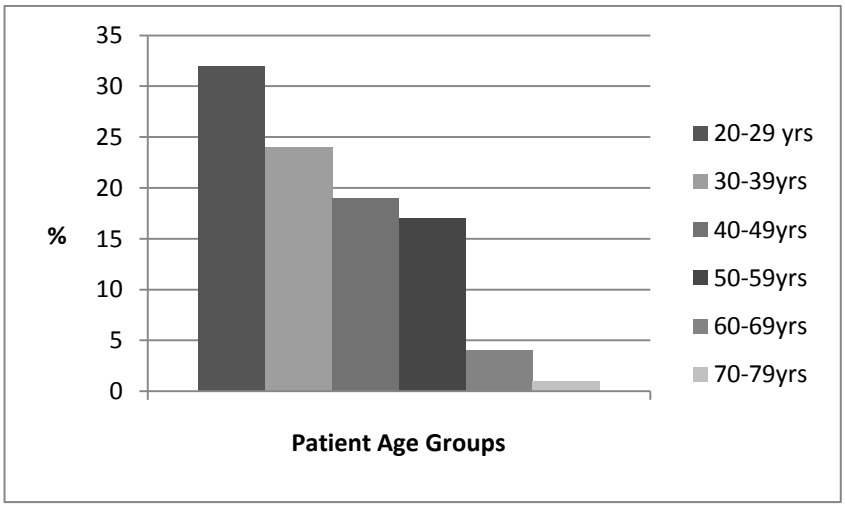
5.1.4(ii) Demographic Profile: Patient Gender and Age

Of those patients attending the SDS in the duration of this study, 53 fitted the inclusion criteria and agreed to participate. Of this group 26.4% were male (n=14) while 73.6% (n=39) were female participants.

The age of participating patients ranged from 20 years to 78 years old with a mean age of 39 years (SD 13.30) and a mode age of 23 years.

In relation to age distribution, 32.1% of patients (n=17) were aged 20 to 29 years, 24.5% (n=13) were aged 30 to 39 years, 18.9% (n=10) fell into the 40 to 49 year old category, while 17% (n=9) were in the 50 to 59 year old age group. In total, only 7.5% (n=4) of all study participants were aged 60 years and over. Age distribution within the sample group is highlighted in Figure 26.

Figure 26: Age Distribution of Patient Participants



5.1.4(iii) Demographic Profile: Patient Barriers to Care

NHS Highland is a remote and rural area. The mean distance that patients travel to reach their dental practice varied from 30.6 miles (SD 19.9) at the Lairg practice to 1.4 miles (SD 0.1) at the Fort William practice. Of these patients, the majority, according to the 2009 Scottish Index of Multiple Deprivation (SIMD), [214]came from less deprived areas of Highland with 87% (n=46) living within the more affluent 20-100% of Scotland's postal regions.

Of the remaining patients, one lived in the most deprived 5% of Scottish areas, two lived in areas SIMD categorised as the most deprived 5-10%, while four patients were within the most deprived 10-15% of areas.

Six of the seven patients living within more deprived areas attended the Invergordon Dental Clinic making up half of the clinic's patient sample. The remaining individual living within the most deprived 0-5% attended Inverness Clinic A.

5.1.4(iv) Patient Clinical Characteristics: Treatment Type

Almost half (49.1%, n=26) of all 53 patients who participated in the study underwent routine conservation on the day of their appointment, while four patients (7.5%) received advanced restorative procedures including root canal treatments, crown preparation and crown fits.

Four (7.5%) patients attended for surgical extractions while a further six (11.3%) patients had routine dental extractions. Three (5.7%) of the 53 patients had prosthetic work on the day of their appointment, while four (7.5%) patients had some form of periodontal treatment.

Of the 53 patients attending for treatment, five (9.4%) complained of a dental problem resulting in one extraction, one crown re-cement, one temporary dressing, a review and one sealant application.

Due to the patient inclusion criteria (requiring treatment appointment sessions only) and the Ethical obligations of this study (information leaflets to be sent out 24 hours before implementation), patients tended to have been seen by the dentist prior to project recruitment. Only eight (15.1%) presented as new patients to the dentist on the day of the study; being referred by another Primary Care dentist or presenting with toothache.

A total of 21 patients (39.6%) had not started their planned treatment until the day of the study, while the remaining 24 (45.3%) had already started their treatment plan with the dentist.

5.1.4(v) Patient Clinical Characteristics: Dental Anxiety

For patient emotional dental state anxiety as measured by STAI-S, the mean score at baseline was 16.23 (SD 3.82) ranging from a minimum score of eight to a maximum score of 23. In relation to the psychological manifestations of dental state anxiety, Heart Rate mean baseline measurement was 81.6 beats per minute (SD 12.33) ranging from 59 bpm to 114 bpm.

For dental trait anxiety, the mean MDAS score for the 53 patients recruited into the project, with no missing data, was 19.70 (SD 3.08) with scores ranging from 11 to 25. The mode score for patients participating in the study was 22.

Of the 53 participants 47 (88.7%) claimed maximum anxiety in at least one of the five MDAS categories. The two categories where the majority of patients claimed maximum anxiety was the local anaesthetic scenario (n=36, 67.9%) and tooth drilling category (n=36, 67.9%). Patients mainly claimed to be very anxious for the remaining MDAS categories; 45.3% (n=24) of participants claimed to be very anxious if they had to attend the dentist tomorrow; 47.2% (n=25) if they were waited in the waiting room for treatment; and 39.6% (n=21) if they had to have a scale and polish.

5.1.4(vi) Randomisation Profile: Clinical and Demographic

Of the 53 participating patients, 26 (49.1%) received the control (MDAS form completed but not handed to the dentist) while 27 (50.9%) received the intervention (MDAS form completed and handed to the dentist).

Of the 27 patients in the experimental group only six were male (22.2%). This was echoed in the control group where 30.8% (n=8) of the 26 patients were male.

In terms of the Scottish Index of Multiple Deprivation Score, in the control group five of the 26 individuals (19.2%) came from areas classified as being within the most deprived 20% of Scotland, while the experimental group had two (7.4%) individuals that came from similarly classified areas.

The mean distance travelled by patients attending the six clinics involved in the study were also similar. Patients who received the intervention travelled on average 15 miles (SD 17.8) to attend while those who received the control travelled 11.9 miles (SD 14.2), with the majority of both groups travelling under 10 miles for their dental treatment.

In terms of patient anxiety, the mean dental trait anxiety of both experimental and control groups as measured by MDAS was 19.3 (SD 3.4) and 21.1 (SD 2.7) respectively. State anxiety was however slightly higher in the control group, with a baseline measure of 16.9 (SD 3.3) while the mean experimental state anxiety was recorded as 15.7 (SD 4.2).

Heart Rate for both groups was comparable at 81.9 (SD 11.7) for those patients entered into the experimental group and 81.3 (SD 13.2) for the control group.

Table 24 summarises the results of the main baseline measures for patient demographic profile and dental anxiety.

Table 24: Summary of Patient Anxiety and Demographics in relation to Randomised Group

	Experimental Group (n=27)	Control Group (n=26)
Age	39.11 (SD 13.54)	38.35 (SD 13.30)
Gender	6 (22%) Male; 21 (78%) Female	8 (30%) Male; 18(70%) Female
SIMD (least deprived 20-100%)	25 (92.6%)	21 (80.8%)
Travel	15.02 miles (SD17.77)	11.96 mile (SD 14.23)
MDAS Total	19.30 (SD 3.37)	21.12 (SD 2.75)
Scored 5 (Extreme anxiety):	4 (14.8%)	3 (11.5%)
Attending dentist tomorrow	2 (7.4%)	4 (15.4%)
Waiting for treatment	18 (66.7%)	18 (69.2%)
Tooth drilled	6 (23%)	5 (20%)
Scale and Polish	19 (70.4%)	17 (65.4%)
Local anaesthetic		
STAI-S Total	15.67 (SD 4.24)	16.88 (SD 3.30)
Heart Rate	81.93 (SD11.71)	81.27 (SD13.17)

In terms of reason for attendance, the majority of both groups attended for routine conservation on the day of their appointment, with 38.5% (n=10) of the control group and 59.3% (n=16) of the experimental group. All emergency appointments occurred in the experimental group with five of the 27 patients (18.5%) attending due to dental or oral problems.

In relation to the spread of dental treatment between groups, two patients in both the experimental (7.4%) and control (7.7%) group received advanced conservation treatment; three routine tooth extraction (11.1% experimental and 11.5% control); and two periodontal treatment (7.4% experimental and 7.7% control). Both groups also contained 18 patients (66.7% experimental and 69.2% Control) who received local anaesthetic for their treatment.

In relation to surgical tooth extractions, the majority of patients receiving this treatment was within the control group (3, 11.5%) as opposed to the experimental group (1, 3.7%). This also applied to those receiving prosthetic treatment (3.7% experimental and 7.7% control).

Of those who were due for treatment but were instead reviewed by the dentist two patients within the experimental group (7.4%) and three within the control 11.5%).

Scale and polish was administered by dentists mainly in the control group (6, 23.1%) while the drill was used comparably between the groups (59.3% experimental and 57.7% control). A summary of treatment per group is highlighted in Table 25.

Table 25: Summary of Treatment Received per Randomised Group

	Experimental Group (n=27)	**Control Group (n=26)**
Local Anaesthetic Administered	18 (66.7%) Yes; 9 (33.3%) No	18 (69.2%) Yes; 8 (30.8 %) No
Treatment Received		
Routine Conservation (e.g. restorative filling of any type)	16 (59.3%)	10 (38.5%)
Advanced Conservation (e.g. root treatment)	2 (7.4%)	2 (7.7%)
Routine Tooth Extraction	3 (11.1%)	3 (11.5%)
Surgical Tooth Extraction	1 (3.7%)	3 (11.5%)
Prosthetic Treatment (e.g. full or part dentures)	1 (3.7%)	2 (7.7%)
Periodontal treatment	2 (7.4%)	2 (7.7%)
Review instead of treatment	2 (7.4%)	3 (11.5%)
Scale and Polish Administered	2 (7.4%) Yes; 25 (92.6%) No	6 (23.1%) Yes; 20 (76.9%) No
Dental Drill Used (excludes tooth polishing)	16 (59.3%) Yes; 11 (40.7%) No	15 (57.7%) Yes; 11 (42.3%) No

Patient age and anxiety levels at baseline were further investigated to ensure both groups were indeed similar, the means of each continuous variable, was compared. An in dependant t-test was used to investigate if there was a significant difference between the two samples.

The result of the independent t-test showed that at the 5% significance level both the control and experimental groups were indeed equivalent (See Table 26).

Table 26: Experimental and Control Group Anxiety Comparison at Baseline

	t	Degrees of freedom	P	Mean Difference	Standard Error Difference	t-test for Equality of 95% Confidence Interval	
						Lower	Upper
Age	-0.21	51	0.84	-0.76	3.69	-8.17	6.64
STAI-S	1.16	51	0.25	1.22	1.05	-0.88	3.32
HR	-0.19	51	0.85	-0.66	3.42	-7.52	6.21
MDAS	0.97	51	0.34	0.82	0.85	-0.88	2.52

STAI-S= Spielberger State Anxiety Inventory-State
HR= Heart Rate
MDAS= Modified Dental Anxiety Score

5.1.5 Conclusion of Recruitment Flow & Baseline Differences

This section of the chapter not only highlights the challenges faced in recruitment and retention of both patients and dental teams but demonstrates their demographic and clinical profile.

Both the experimental and control groups appear to be well matched in relation to demographics and the clinical treatments undertaken.

5.2. Study One

5.2.1 Introduction

Study One details the experimental part of this mixed methods study design. It investigates the effectiveness of an experimental intervention (the handover of the completed MDAS to the dentist) in influencing patient health outcome (dental state and trait anxiety).

This study builds on the published work of Dailey et al,[17] who by undertaking a two-armed randomised controlled trial in Primary Dental Care, demonstrated a significant drop in patient dental state anxiety (using STAI-S, an emotional state anxiety measure) when the MDAS form was handed directly to the dentist.

To explore these results further and also determine any longer term consequences in patient dental anxiety, the essential elements of the randomised controlled trial undertaken by Dailey et al.,[17] were replicated. This was completed by using a randomised cross-over study as detailed in Chapter 4. The study had the ability to investigate further not only changes in patient emotional dental state anxiety but also (i) physiological manifestations of state anxiety and (ii) trait or longer term dental anxiety status.

5.2.2 Aim of Study One

The aim of Study One is therefore to address Objective One (see Chapter 3.2) i.e. to determine the longer term effect of the patient providing the dentist with their dental anxiety questionnaire. Although longer term effects on dental anxiety were the main focus, short term effects were examined to test for replication of the Dailey et al.,[17] and Hull et al.,[18] studies. These short term effects were assessed by state self reported and physiological measures. The STAI-S and Heart Rate change scores will be employed as secondary outcome measures. The change in MDAS will function as the primary outcome measure.

The sub-objectives of this study were to:

1. Assess the short term change in dental state anxiety as measured by STAI-S.
2. Assess the short term change in the physiological manifestations of dental state anxiety as measured by Heart Rate.
3. Assess the change in a longer term effect on dental anxiety status (dental trait anxiety) as measured by MDAS.

In order to complete the Objective One and its sub-objectives the author will compare experimental and control groups by testing the original hypotheses outlined in Chapter 3.1, that:

1. (*Hypothesis One*) In the population of dentally anxious adults attending Salaried Dental Practices (SDPs) in NHS Highland, there is no difference in mean anxiety score (as assessed by STAI-S and Heart Rate) of dentally anxious adults who have given their MDAS questionnaire to the dentist and those who did not.

2. (*Hypothesis Two*) Also in this population of dentally anxious adults attending SDPs in NHS Highland, there is no difference in dental anxiety score (as assessed by MDAS) of dentally anxious adults who have given their MDAS questionnaire to the dentist and those who did not at three month follow-up.

To consider these hypotheses, change scores for dental state anxiety, both emotional (STAI-S) and physiological (Heart Rate) and for dental trait anxiety (MDAS) were considered.

5.2.3 Study One Methods and Analysis

Chapter 4 details the methodology used in undertaking Study One, the randomised cross-over element of this mixed methods study. Table 27 summarises study components using the PICO method.

Table 27: Summary of Study One Methodology

Population	NHS Highland Primary Care SDP patients
Intervention	Completed MDAS form handed over directly to dentist
Comparison	Completed MDAS form left with researcher/author
Outcomes	Primary Outcome: MDAS Score at 3 months Secondary Outcomes: STAI-S Score and Heart Rate post-treatment

In terms of participant flow, of the 1096 patient invitations sent out, only 53 patients fitted the inclusion criteria and agreed to take part in the study. Of these individuals only 47 completed the study in its entirety i.e. completed the three month MDAS outcome measurement.

Missing outcome measures were addressed by averaging the total change within each surgery's control or experimental group, and substituting the missing data with an appropriate average replacement value. A sensitivity analysis was completed in addition using only completed data sets.

This was done to ensure no substantial discrepancy in the comparison of pre and post treatment as well as three month follow-up.

All outcome measurements were analyzed by using SPSS version 18. Summary statistics were calculated to include frequencies and, where appropriate, means and standard deviations; t- tests were calculated to investigate differences between the groups.

A mixed effects analysis of covariance on the MDAS change scores (primary outcome variable) and STAI-S change scores (secondary outcome variable) to test for the group effect, controlling for gender and age was conducted.

5.2.4 Results: Effect of Intervention on Patient Dental Anxiety

This section investigates the effect of the experimental intervention (MDAS questionnaire handover) on post-treatment health outcome measures (dental state and trait anxiety). Control and experimental group mean change scores were compared to investigate:

- Hypothesis One- by considering emotional state anxiety measures using STAI-S (subsection 5.2.4 (i)) and Heart Rate measurement (subsection 5.2.4.(ii))
- And Hypothesis Two- the longer term trait anxiety effects of form handover as measured by MDAS (subsection 5.2.4 (iii)).

The entire sample of 53 dentally anxious patients was investigated; missing values for STAI-S, Heart Rate and MDAS are detailed in Section of 5.2.5; treated and computed as detailed in Section 5.2.3

5.2.4(i) Effect of Intervention on Emotional Dental State Anxiety as Measured by STAI-S

In terms of the difference between the experimental group and the control group, the difference between pre and post-treatment scores were analysed.

As highlighted in Table 28, the mean score for the experimental group pre-treatment was 15.67 (SD 4.24), ranging from 8-23, while post treatment the mean score was 13.04 (SD 3.97), with a range of six to 21.

Table 28: Comparison of Pre and Post Treatment Mean STAI-S Scores

N=27	**Experimental Group** (MDAS form handed over to Dentist)				
	Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
Pre-STAI-S (baseline)	15.67 (4.24)	8-23	14.07-17.27	3.13 (26)	0.004
Post-STAI-S	13.04 (3.97)	6-21	11.55-14.54		

N=26	**Control Group** (MDAS form not handed over to Dentist)				
	Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
Pre-STAI-S (baseline)	16.88 (3.30)	13-23	15.61-18.15	3.82 (25)	0.001
Post-STAI-S	14.35 (3.20)	11-24	13.12-15.58		

The mean score for the control group pre-treatment was 16.88 (SD 3.30) ranging from 13-23 while the post treatment mean was 14.35 (SD 3.20), with a range of 11 to 24.

The mean values were compared using a paired t-test based on the assumption that the differences observed in both pre and post STAI-S measurements have an approximately normal distribution.

There was a statistically significant mean reduction between pre and post STAI-S scores for both the control (reduction of 2.54; 95% CI 1.17 to 3.91; $P<0.05$), and experimental group (reduction of 2.63; 95% CI 0.90 to 4.45; $P<0.05$).

In other words, dentally anxious patients who handed over their MDAS form and those who did not, both experience a reduction in dental state anxiety as measured by STAI-S.

The mean STAI-S change score for both the experimental and control groups were then compared using an independent t-test. This was done once Levene's test for equality indicated that equal variances could be assumed (P>0.05).

Table 29 highlights that both the experimental and control group mean change scores were not significantly different (0.09; 95% CI -2.25 to 2.07; P>0.05) indicating that in terms of STAI-S, Hypothesis One cannot be rejected at the 5% significance level.

Table 29: Results of Independent T-Test Comparing Experimental and Control Mean STAI-S Change Score

	t	Degrees of freedom	P	Mean Difference	Standard Error Difference	t-test for Equality of 95% Confidence Interval	
						Lower	Upper
STAI-S difference	-0.08	51	0.93	-0.09	1.07	-2.25	2.07

5.2.4(ii) Effect of Intervention on Physiological Manifestations of Dental State Anxiety

To consider the issue of dental state anxiety further, the physiological aspect of patient dental state anxiety was investigated. This was done by considering changes in mean patient Heart Rate measure.

In this subsection the mean post-treatment Heart Rate measurement for each group will be considered. The pre and post mean Heart Rate measurement are summarised in Table 30.

Table 30: Comparison of Pre and Post Treatment Mean Heart Rate Measurements

N=27	**Experimental Group** (MDAS form handed over to Dentist)				
	Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
Pre-HR (baseline)	81.93 (11.71)	61-103	77.51-86.35	3.25 (26)	0.003
Post-HR	74.07 (10.02)	48-90	70.92-77.85		

N=26	**Control Group** (MDAS form not handed over to Dentist)				
	Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
Pre-HR (baseline)	81.27 (13.17)	59-114	76.21-86.33	1.24 (25)	0.22
Post-HR	77.27 (11.94)	55-97	72.68-81.86		

The mean Heart Rate measurement for the experimental group before treatment was 81.93 bpm (SD 11.71) and following treatment was 74.07 bpm (SD 10.02) while the mean of the control group before treatment was 81.27 bpm (SD 13.17) and after treatment 77.27 bpm (SD 11.94).

To consider if the difference between pre and post treatment Heart Rate measures in each group was significant, the author undertook a paired t-test. The results of the t-test are again based on the assumption that the differences observed in both pre and post Heart Rate measurements have an approximately normal distribution.

According to these results, it appears that dentally anxious patients within the experimental group (i.e. those patients who handed their completed MDAS forms to the dentist) experienced a significant mean reduction in Heart Rate immediately following treatment (reduction of 7.85; 95% CI 2.88 to 12.82; $P<0.05$).

The reduction in Heart Rate within the control group was however not significant (reduction of 4.00; 95% CI -2.62 to 10.62; P>0.05).

According to the results of this test, there appears to be a potential link between the intervention and a significant reduction in dental state anxiety. To investigate this fully the experimental group mean difference was compared to the control group mean difference using an independent t-test, once Levene's test for equality of variances had been satisfied (P>0.05). Results of the independent t-test are highlighted in Table 31.

Table 31: Results of Independent T-Test Comparing Experimental and Control Mean Heart Rate Change

	t	Degrees of freedom	P	Mean Difference	Standard Error Difference	t-test for Equality of 95% Confidence Interval	
						Lower	Upper
HR difference	-0.96	51	0.34	-3.85	4.00	-11.88	4.18

According to these results, the two groups appear to be similar with both mean change scores not significantly different statistically (-3.85; 95% CI -11.88 to 4.18; P>0.05).

This therefore indicates that Hypothesis One, stating no effect of the intervention on state anxiety cannot be rejected at the 5% significance level, for physiological dental state anxiety.

5.2.4(iii) Effect of Intervention on Patient Dental Trait Anxiety

This subsection of the study addresses whether the intervention had an effect on patient dental trait anxiety levels at three month follow-up. Details of both pre-treatment and three month mean scores, per group are summarised in Table 32.

Table 32: Comparison of Pre and Post Treatment Mean MDAS Scores

N=27	**Experimental Group** (MDAS form handed over to Dentist)				
	Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
Pre-MDAS (baseline)	19.30 (3.37)	11-25	18.03-20.57	3.76 (26)	0.001
3 Month MDAS	15.67 (5.29)	5-25	13.67-17.66		

N=26	**Control Group** (MDAS form not handed over to Dentist)				
	Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
Pre-MDAS (baseline)	20.12 (2.75)	12-24	19.06-21.18	5.85 (25)	<0.001
3 Month MDAS	15.04 (4.55)	6-21	13.29-16.79		

The mean MDAS score for the experimental group pre-treatment was 19.30 (SD 3.37) and at three months was 15.67 (SD 5.29) while the mean of the control group before treatment was 20.12 (SD 2.75) and after treatment was 15.04 (SD 4.55).

To consider if the difference in each group between baseline (pre-treatment) and three month follow-up was significant, a paired t-test was undertaken on the assumption that the differences observed in both pre and post MDAS measurements have an approximately normal distribution.

According to these results, it appears that both experimental (reduction of 3.63; 95% CI 1.64 to 5.61; P<0.05) and control groups (reduction of 5.01; 95% CI 3.29 to 6.85; P<0.05) exhibit a significant decrease in dental trait anxiety.

To investigate this result fully the experimental group mean difference was compared to the control group mean difference using an independent t-test. This was undertaken once Levene's test for equality of variances had been satisfied (P>0.05) and is highlighted in Table 33.

Table 33: Results of Independent T-Test Comparing Experimental and Control MDAS Mean Change Scores

	t	Degrees of freedom	P	Mean Difference	Standard Error Difference	t-test for Equality of 95% Confidence Interval	
						Lower	Upper
MDAS difference	1.11	51	0.27	1.45	1.30	-1.16	4.06

According to these results, the two groups appear to be similar with both MDAS mean change scores not significantly different (1.45; 95% CI -1.16 to 4.06; P>0.05).

This therefore indicates that Hypothesis Two, stating no effect of the intervention on dental trait anxiety, cannot be rejected at the 5% significance level. In other words, the intervention also appears to have had no effect on patient's longer term experience of dental anxiety.

5.2.5. Results: Patient Post Treatment Anxiety Measures

Following consideration of intervention effect, the post-treatment emotional dental state anxiety (STAI-S), physiological manifestations of dental state anxiety (Heart Rate) and trait dental anxiety outcomes (MDAS) of the entire sample of 53 dentally anxious patients was investigated. This was done to consider whether (i) emotional dental state anxiety and (ii) Heart Rate decreased from baseline following dental treatment, and (iii) if trait dental anxiety decreased over time (i.e. three months from baseline).

5.2.5(i) Patient Post-Treatment Emotional Dental State Anxiety as Measured by STAI-S

The emotional dental state anxiety of the patient sample was measured immediately after their dental treatment using the Spielberger State-Trait Anxiety Inventory (STAI-S). For some anxious patients (n=4) however, who were too distressed to have the post-treatment measurements taken, no post treatment STAI-S value could be obtained. In such cases, the author addressed the missing data as highlighted in section 5.2.3.

There were three missing control values and one missing experimental value. Inverness clinics A and B both had one missing value (with one clinic missing a control value and the other an experimental value) while the Invergordon clinic had the remaining two missing control values.

The post treatment STAI-S mean for all 53 patients participating in the study was 13.68 (SD 3.64) with a range of 6-24, while from baseline results the mean pre-treatment STAI-S score for the entire sample was 16.23 (SD 3.82). By undertaking a paired t-test, the author aimed to consider whether this difference indicated a significant change in state anxiety in the sample group following treatment.

The results of the t-test, based on the assumption that the differences observed in both pre and post STAI-S measurements have an approximately normal distribution, are highlighted in Table 34(i).

Results demonstrate a statistically significant mean difference between pre and post STAI-S scores for the entire sample (reduction of 2.58; 95% CI 1.52 to 3.65; P<0.001), indicating that overall, dentally anxious patients experienced a reduction in state anxiety on completion of their treatment appointment.

Table 34: Results of Paired T-Tests Comparing Pre and Post Mean STAI-S, Heart Rate and MDAS Scores

	Total Group n=53	Pre-treatment Scores Mean (SD)	Post-treatment Scores Mean (SD)	t (df)	P
(i)	Dental State Anxiety (STAI-S)	16.23 (3.82)	13.68 (3.64)	4.86 (52)	<0.001
(ii)	Heart Rate (bpm)	81.60 (12.33)	75.64 (11.02)	2.98 (52)	0.004

	Total Group n=53	Pre-treatment Scores Mean (SD)	3 Month Score Mean (SD)	t (df)	P
(iii)	Dental Trait Anxiety (MDAS)	19.70 (3.08)	15.36 (4.90)	6.65 (52)	<0.001

5.2.5(ii) Patient Post-Treatment Physiological Manifestations of Dental State Anxiety

This also appears to be the case with regard to the physiological manifestation of patient state anxiety (Heart Rate). Once missing values were treated and computed as detailed in Section 5.2.3, the pre and post treatment values were compared.

The mean post-treatment Heart Rate for the sample group was 75.64 bpm (SD 11.02), and ranged from 48 to 97 bpm, compared to the baseline measure of 81.6 bpm (SD 12.33) with measurements ranging from 59 bpm to 114 bpm. There was a statistically significant difference between pre and post mean Heart Rate scores for the entire sample (reduction of 5.96; 95% CI 2.04 to 9.88; $P<0.05$), indicating that overall, dentally anxious patients experienced a reduction in Heart Rate on completion of their treatment appointment. The results of the paired t-test are highlighted in Table 34 (ii).

5.2.5(iii) Patient Dental Trait Anxiety Three Month Post-Treatment

In terms of dental trait anxiety, following the completion of the baseline Modified Dental Anxiety Score (MDAS) prior to dental treatment, the patient was contacted approximately three months later to complete another MDAS form.

Of the 53 patients who initially entered the study, a total of 47 completed the three month post-treatment MDAS questionnaire. The six patients who did not complete the study were evenly distributed between both experimental (n=3) and control groups (n=3).

The missing values were distributed between the Inverness clinic B (n=1), the Invergordon Clinic (n=2) and the Grantown-on-Spey clinic (n=3). In Inverness clinic B, the missing value was experimental, while both missing values in the Invergordon clinic were control values. In the Grantown-on-Spey clinic, one control and two experimental values were missing. Missing values were treated and computed as detailed in Section 5.2.3.

The three month follow-up mean for all 53 patients participating in the study was therefore calculated to be, 15.36 (SD 4.90) with a range of 5-25, while from baseline the mean pre treatment MDAS score for the entire sample was 19.70 (SD 3.08). There was a statistically significant difference between pre-treatment (baseline) and three month MDAS scores for the entire sample (reduction of 4.34; 95% CI 3.03 to 5.65; P<0.001), indicating that overall, dentally anxious patients experienced a reduction in their trait dental anxiety over a three month period following their initial treatment (Table 34(iii)).

5.2.6 Discussion of Study One

According to these results, the experimental intervention (the handover of the completed MDAS questionnaire to the dentist), had no statistically significant effect on either patient dental state anxiety (emotional and physiological) or patient dental trait anxiety, with both Null Hypotheses not rejected at the 5% significance level.

This result was unexpected, and was not consistent with the results of the Dailey et al.,[17] and Hull et al.,[18] studies, which showed a significant difference in emotional dental state anxiety (STAI-S score) in patients handing their completed MDAS forms to the dentist (Experimental group).

To investigate this null effect further the author considered the intricacies of each individual outcome: STAI-S, Heart Rate and MDAS.

All dental anxiety measures, (both state and trait) demonstrated a statistically significant mean difference between pre and post treatment outcomes. This reduction may be attributed to the inevitable decrease in dental anxiety experienced by dentally anxious patients following the completion of a treatment episode and indeed the establishment of patient-dentist relationships over time.

There was some support for intervention effect. A statistically significant decrease in experimental group mean Heart Rate highlighted at least, partial support for the Dailey et al.,[17] results and indeed the wider health communication evidence base (see Chapter 2.3, the Systematic Review).

These results were somewhat disappointing. The lack of an effect may be attributable to a number of factors including: choice of study design, carry-over effects or sample size. Their relevance can only be supported if the study being undertaken is an exact implementation of study protocol. In other words, all participants involved in the study are behaving in exactly the way that they are expected to.

In randomised controlled trial structure, this is the assumption. This study however employed a mixed methods design. The advantage was to allow the randomised cross-over study to run in tandem with the observational study. This additional methodological procedure provided another important dimension to outcome interpretation. In this case the observations were able to record the actual participant behaviour. Hence, the fidelity to the intervention could be assessed rather than assumed.

It may be hypothesised therefore that the results of Study One may have been due to deviations from the expected procedure of the delivery of the intervention. Indeed, a deviation in MDAS form handover may influence whether the patient was able to actually provide the dentist with the relevant information about their anxiety. Therefore Study One results may be due to a deviation in how MDAS information was used by the dentist, hence effecting dentist behaviour and communication effectiveness.

To investigate this hypothesis further, the videos were analysed to provide observational qualitative and quantitative data. This was done first to consider implications relating to patient and dentist behaviour and secondly the emotional content of the patient-dentist dyad.

5.3 Study Two

5.3.1 Introduction

Study Two, considered the observational element of the mixed methods design. It investigated the clinical context in which the randomised cross-over trial was set. This allowed the results from the experimental element (Study One) to be explained through its context detailed in Study Two.

Results of Study One highlighted an inconsistency relating to the original Dailey et al.,[17] study. These inconsistencies in dental anxiety outcome will now be investigated using the observational part of the study.

Both non-verbal and verbal aspects were analysed in relation to two main topics: first, the behaviour elicited by both patient and dentist (Section 5.3.4); and secondly, the emotional content expressed within the dental dyad (Section 5.3.5).

To ensure a cohesive outcome, both main topics were studied using not only a quantitative analysis but also qualitative vignettes. By presenting the results of this section in this way, the author hoped to provide a comprehensive backdrop including a set of possible and credible explanations for Study One outcomes.

5.3.2 Aim of Study Two

The aim of Study Two was to explore the expressed verbal and non verbal communication present in the dentist-patient interaction, with a particular emphasis on the initial first phase of the appointment in the dental surgery. The focus on the initial interaction between patient and dental staff in the surgery was to closely inspect the MDAS handover and the resulting discussion between the participants.

The behavioural objectives of this study (i.e. what happened during MDAS form handover) were to:

1. Assess the change in dental anxiety (as measured by STAI-S, Heart Rate and MDAS) in relation to patient handover behaviour [Section 5.3.4(ii)].
2. Assess the change in dental anxiety (as measured by STAI-S, Heart Rate and MDAS) in relation to patient perceived, dentist behaviour i.e. the patient observes the dentist looking at the MDAS form [Section 5.3.4(iv)].
3. Assess the change in dental anxiety (as measured by STAI-S, Heart Rate and MDAS) in relation to actual dentist behaviour (Section 5.3.4 (vi)].
4. Provide a contextual framework for the patient-dentist handover behaviour using qualitative vignettes [Section 5.3.4(iii), (v) and (vii)].

The affective objectives of this study (i.e. what was 'said' during MDAS form handover) were to:

1. Assess the change in dental anxiety (as measured by STAI-S, Heart Rate and MDAS) in relation to patient cues and concerns [(Section 5.3.5(i)].

2. Assess the change in dental anxiety (as measured by STAI-S, Heart Rate and MDAS) in relation to how the dentist responds to patient cues and concerns [(Section 5.3.5(ii)].
3. Provide a contextual framework for the patient-dentist dyad during the handover phase using qualitative vignettes within each Section.

5.3.3 Study Two: Methods and Analysis

Chapter 4 detailed the methodology used in undertaking Study Two, the observational element of this mixed methods design. Study Two ran in conjunction with Study One, the randomised cross-over trial. All 53 recruited patients completed the observational element of the study, with both control and experimental groups having their dental treatment appointment videoed. Video quality was assessed prior to coding.

Observer XT (version 8) software was used to enable coding directly from the video recordings, using two separate coding systems:

Coding System One (detailed in Section 5.3.3 (i)): was used to investigate the behavioural aspect of the relationship; coding observed individual patient-health professional actions.

Coding System Two: investigated the emotional content of the dyad using the Verona CoDES a validated and reliable European coding system[215, 216] (see Section 5.3.3 (ii)).

As part of the quantitative investigation; type, duration and frequency of emotions (using Verona CoDES) and behaviours (coded individual actions) were recorded and analysed using SPSS version 18.

Summary statistics were calculated to include frequencies and where appropriate, means and standard deviations; t-tests were calculated to investigate differences between groups. While for the qualitative investigation, dyadic vignettes of both behavioural and affective patient-dentist interactions are presented.

5.3.3(i) Coding System One: Behavioural Analysis

The behaviour expressed in the dyad was investigated using an author generated coding system (see Table 35). This system considered the various actions of both patient and dentist during MDAS form handover. Expressed behaviour was coded using the coding elements detailed in Table 35. Codes may be categorized as Point or Duration events. Unlike Point codes that stand alone, Duration codes are composed of two mutually exclusive events; a positive code, used when the event is occurring e.g. 'holds' and a negative code when it is not, e.g. 'does not hold'.

This coding scheme was developed by the author by initially viewing all dentist-patient video recordings. Predominant behaviours were noted and then a list of definitions relating to each patient and dentist behaviour, drawn up. As explained in Section 5.3.4(i), a timeframe of two minutes was established for the video coding duration.

Table 35: Behaviour Coding System

Code	Event Type	Description
Start	Point	The moment the patient crosses the surgery threshold.
Holds	Duration	Where the individual holds the MDAS form. This code may be allocated to any individual.
Hands over	Point	The moment the MDAS form is handed over from one individual to another. Sub-codes for this category refer to the individual receiving the form.
Places	Point	The instant when the MDAS form is placed on the surgery work surface.
Looks	Duration	When the printed side of the MDAS form is looked at by the dentist.
Sees	Duration	When the patient observes the dentist looking at the printed side of the MDAS form.
Stop	Point	Termination of coding at 2 minutes.

5.3.3(ii) Coding System Two: Emotional Content Analysis using Verona CoDES

Verona CoDES, developed by the Verona Network on Sequence Analysis was the coding system used to assess health provider (dentist) behaviour in relation to expressed patient emotion. The Verona CoDES are composed of dyadic couplets, starting with a patient expression of emotion which can be prompted by the dentist (or health professional) and can be elicited either directly as in a verbal concern or indirectly by a verbal or non-verbal cue.

According to the Verona coding scheme a 'concern' is a "clear verbalisation of an unpleasant emotional state" while a 'cue' is an "Expression in which the emotion is not clearly verbalised or might be present".[217]

The response of the dentist to this patient prompt provides the second part to the couplet. Dentists can either respond explicitly or non-explicitly to the cue or concern. According to the Verona coding scheme an 'explicit' code is "any response which specifically mentions either the content/topic or the emotion in the cue or concern or both"; while a non-explicit code can be defined as "any response which *does not* explicitly mention either the content or the emotion of the cue or concern".[215]

These responses are further specified by either 'closing space' or 'providing space'. According to the Verona Code system, 'providing space' is "any intervention which gives space for further disclosure of the cue/concern expressed by the patient"; while 'reducing space' can be defined as "any response or intervention which reduces the space for or closes down further disclosure about the cue or concern expressed by the patient".[215]

In this thesis the results of the Verona Code analysis can be seen in Section 5.3.5. The system was learnt from detailed reading of the manuals and instruction from GH, who is a member of the Verona CoDES group which developed the system over the past seven years.

5.3.4 Behaviour Study Results

On entry to the dental surgery, experimental group patients were instructed to hand their MDAS form directly to the dentist, hence providing the dentist with information relating to the patient's reported dental anxiety. The provision of such information had been claimed by Dailey et al.,[17] to have reduced patient's reported state anxiety levels.

The reason for this reduction hypothesised by Dailey et al.,[17] was either thought to be attenuated by (i) patient expectation (in that the patient now expects the dentist to now be aware of their dental anxiety) or (ii) dentist's behaviour (in that the MDAS form facilitates more effective discourse regarding a patient's dental anxiety). In other words, the results of the Dailey study are intrinsically related to the "handing over behaviour" elicited by the patient.

Study One showed little difference between patients in the experimental group compared to those in the control group. The reason for this, in relation to patient-dentist behaviour was examined. In essence the dentist-patient interaction was unpacked to examine the behaviours in relation to the handover and examination of MDAS.

5.3.4(i) Development of Analysis Timeframe

On average MDAS form handover occurred 4.27 seconds (SD 2.21) after the patient crossed the surgery threshold.

To ensure that each observation included the handover behaviour and any associated behaviours, the first two minutes of each video recording was analysed. This resulted in the initial phase of the dental treatment appointment or 'History taking' element of the healthcare interaction,[80] being investigated.

Collated video recordings of all 27 experimental patients were assessed and deemed of suitable quality and duration. Videos were analysed to consider the actual behaviours elicited by both patient and dentist in relation to the initial information transfer i.e. handing the MDAS form to the dentist.

5.3.4(ii) Quantitative Analysis: Adherence to MDAS Handover Protocol

According to the study protocol, patients within the experimental group were instructed to hand their completed MDAS form directly to the dentist.

On completion of the treatment appointment, patients had post-treatment state anxiety measures recorded. At this stage, no problem was identified by patients regarding the 'handover' element of the study.

On review of the videos however, this element did appear to be problematic. Of the 27 patients instructed to hand their form directly to the dentist, only 19 (70.4%) successfully completed the task.

Two patients (7.4%) forgot to hand their MDAS form over to the dentist, while a further three patients (11.1%) handed their MDAS form to the Dental Nurse instead.

The remaining three patients (11.1%) did not hand their form over but instead placed it on the surgery work surface prior to sitting on the dental chair. All eight patients were focused around two dental surgeries only.

To consider whether this deviation from the protocol had any influence on Study One outcomes (reported in Section 5.2), the data were analysed in terms of the actual handover behaviour elicited by experimental group patients.

To assess the effect of MDAS form handover, on patient dental anxiety, a comparison was made between those experimental group patients who handed their form directly to the dentist (the Adherent Experimental Group) and those who did not (the Non-adherent Experimental Group).

These individual groups were considered in relation to each other and the control group. To investigate the relevance of change scores, an independent t-test was undertaken between each group, once Levene's test for equality of variances had been satisfied for each variable ($P>0.05$).

Table 36, highlights the comparison of mean dental anxiety change scores (Heart Rate, STAI-S and MDAS) of patients who adhered to the study protocol (the Adherent Experimental Group) compared to those who did not (the Non-Adherent Experimental Group). This will be termed Comparison One and will be followed by a comparison of each of the experimental groups (Adherent and Non-Adherent) with the control group, Table 37 and Table 38, Comparison Two and Comparison Three respectively.

Table 36: Comparison One: Mean Change Scores in Experimental Adherent and Non-Adherent Groups

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Adherent N=19	7.74 (10.96)	-9-30	2.81-12.67	-0.07 (25)	0.94
	Non-Adherent N=8	8.12 (16.65)	-9-45	-3.42-19.66		
STAI-S	Adherent N=19	3.74 (4.27)	-3-11	1.82-5.66	2.17 (25)	0.04
	Non-Adherent N=8	0.00 (3.55)	-5-5	-2.45-2.45		
MDAS	Adherent N=19	3.76 (3.98)	-4-14	1.97-5.53	0.25 (25)	0.80
	Non-Adherent N=8	3.25 (7.25)	-8-17	-1.77-8.27		

*Positive change scores indicate a reduction in dental anxiety

Table 37: Comparison Two: Mean Change Scores in Experimental Adherent and Control Groups

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Adherent N=19	7.74 (10.96)	-9-30	2.81-12.67	0.86 (43)	0.39
	Control N=26	4.00 (16.38)	-31-33	-2.29-10.29		
STAI-S	Adherent N=19	3.74 (4.27)	-3-11	1.82-5.66	1.05 (43)	0.30
	Control N=26	2.54 (3.38)	-7-9	1.25-3.83		
MDAS	Adherent N=19	3.76 (3.98)	-4-14	1.97-5.53	-1.00(43)	0.32
	Control N=26	5.08 (4.23)	-1-13	3.38-6.78		

*Positive change scores indicate a reduction in dental anxiety

Table 38: Comparison Three: Mean Change Scores in Experimental Non-Adherent and Control Groups

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Non-Adherent N=8	8.12 (16.65)	-9-45	-3.42-19.66	0.62(32)	0.54
	Control N=26	4.00 (16.38)	-31-33	-2.29-10.29		
STAI-S	Non-Adherent N=8	0.00 (3.55)	-5-5	-2.45-2.45	-1.83(32)	0.08
	Control N=26	2.54 (3.38)	-7-9	1.25-3.83		
MDAS	Non-Adherent N=8	3.25 (7.25)	-8-17	-1.77-8.27	-0.87(32)	0.39
	Control N=26	5.08 (4.23)	-1-13	3.38-6.78		

*Positive change scores indicate a reduction in dental anxiety

Patients who adhered to the handover protocol compared with those who did not (Comparison One), had greater and significant falls in mean STAI-S scores (3.74; 95% CI 0.20 to 7.28; *P*=0.04). No other significant differences were shown in relation to Comparison One (Heart Rate: -0.40; 95% CI -11.51 to 10.73; *P*>0.05); (MDAS: 1.79; 95% CI -0.40 to 3.99; *P*>0.05).

In relation Comparison Two (see Table 37), the Adherent Experimental Group and the control group, no statistically significant differences were shown (Heart Rate; 3.74; 95% CI -5.01 to 12.48; *P*>0.05); (STAI-S: 1.20; 95% CI -1.10 to 3.50; *P*>0.05);(MDAS: -0.79; 95% CI -3.89 to 2.32; *P*>0.05).

While Comparison Three (see Table 38), the Non-Adherent Experimental and the control group, echoed these results (Heart Rate: 4.12; 95% CI -9.42to 17.67; *P*>0.05), (MDAS: -0.79; 95% CI -3.89 to 2.32; *P*>0.05); (STAI-S: -2.54; 95% CI -5.36 to 0.28; *P*>0.05).

The non-adherent group had no change in STAI-S mean scores compared to the other two groups who showed relative significant reductions in state self-reported anxiety.

5.3.4(iii) Qualitative Vignettes: Adherence to Handover Protocol

To further unpack the quantitative results highlighted in Section 5.3.4 (ii), differences within the experimental group (Adherent and Non-Adherent groups) were viewed contextually using qualitative vignettes detailing individual patient-dentist handover behaviour. A quantitative vignette is a summary of the behavioural exchange not fully expressed in the behavioural coding system. In cases where patients adhered to MDAS handover protocol i.e. direct patient-dentist handover occurred, the behavioural vignettes were similar.

Examples of Adherent Experimental Group Vignettes

Vignette A: *Patient enters surgery and dentist greets him. Patient stands facing dentist and immediately hands over MDAS form.*

Vignette B: *Patient enters surgery holding MDAS form. Dental team greet patient. Patient walks over to dentist who is seated next to the dental chair and hands over the MDAS form. Dentist thanks patient. Patient turns to put bag on chair next to door, then returns to dental chair and sits down.*

Vignette C: *Patient is greeted by dental team. Patient stands at door holding form looking around to find out, to whom it should be handed. The dentist engages the patient and takes the form from her.*

Vignette D: *Dentist welcomes patient at the door. Patient walks into surgery holding MDAS form. Dentist invites patient to sit in dental chair. Patient walks towards dental chair, turns and hands the MDAS form to the dentist.*

Example of Non-Adherent Experimental Group Vignettes: handover 'forgotten'

Where direct MDAS form handover did not occur, the vignettes appear to follow three key themes:

- the MDAS handover element was 'forgotten' by the patient;
- it was blocked by either the dentist or the dental nurse;
- or it was not adhered to in its entirety.

Vignette E highlights a case where the patient 'forgot' to handover the MDAS form.

Vignette E: *Patient enters surgery with the MDAS form. Dental team greet patient. Patient establishes who is the dentist then sits down on dental chair. Patient does not sit on chair completely but sits with both feet on the floor. Dental nurse immediately interacts with patient to ensure medical history signed and correct. Patient holds MDAS form. Dentist sits next to dental chair waiting for dental nurse to finish. Patient signs medical history form. Dentist gets up and steps forward to engage patient. Patient immediately launches into reason for attendance.*

Patient holds MDAS form as speaks to dentist. Patient moves legs onto dental chair to sit on it completely. MDAS form is still held tightly by the patient.

Example of Non-Adherent Experimental Group Vignettes: Blocking Activity

Blocking of the MDAS form handover is highlighted in the following behavioural vignettes. In vignette F, this activity is undertaken by the dentist while in vignettes G, H and I, the dental nurse blocks MDAS form handover.

Vignette F: *Patient comes into surgery with form, walks over to the dentist who is seated next to the dental chair and tries to handover form. Dentist waves hands and tells patient to keep the form. Patient explains that they have been asked to give the form to the dentist. Dentist is surprised. Patient then places the form down on the work surface near to dentist. No further mention of the form or behaviour related to it occurs.*

Vignette G: *Patient enters surgery with MDAS form. Patient places handbag on chair next to door then turns to try to give the MDAS form to the dental nurse. The dental nurse is unaware. Patient then waves the form between dentist and dental nurse while enquiring to whom the form should be given. While the dentist dries her hands the dental nurse takes the form from the patient and places it on the work surface away from the dentist. The dental nurse tells the patient just to take the form back to the researcher at the end of the appointment. Patient states that the form was meant to be given to the dental team. The dental nurse expresses surprise. The dentist completes drying her hands and steps forward to engage patient. Form ignored.*

Vignette H: *Patient enters surgery with form, waits at the surgery door while establishing eye contact with Dentist. Patient walks towards Dentist with form outstretched. Dental Nurse intercepts patient by stepping forward and instructing patient to place form on work surface. Patient places it on the unit surface near the dentist, walks over to the dental chair and sits down. Form then ignored.*

Vignette I: *Dental Nurse intercepts patient in corridor and takes MDAS form. Patient therefore enters surgery with no form. Nurse enters surgery with form and promptly places it into patient's notes. Dentist is unaware. Form then ignored.*

Example of Non-Adherent Experimental Group Vignettes: Incomplete Handover

The final MDAS form handover theme relates to the patient not adhering to the MDAS handover protocol in its entirety. Here the patient although completing MDAS transfer either gives it to the dental nurse or places it on the surgery work surface without trying to give it to the dentist. Vignettes J and K highlight this behaviour.

Vignette J: *Patient enters surgery holding MDAS form. Dentist (seated) welcomes the patient. Patient responds and places MDAS form on work surface next to Dentist without engaging in eye contact. Patient proceeds to dental chair with fists tightly clenched. Dental Nurse invites her to sit down.*

Vignette K: *Patient enters surgery and walks right over to the dental chair, hands MDAS form to Nurse before sitting down. Nurse places MDAS on the work surface*

5.3.4(iv) Quantitative Analysis: Patient Perceived Dentist Behaviour

Of the 27 patients within the experimental group expected to handover their MDAS form, only 17 (63.0%) actually saw the dentist look at their dental anxiety score.

The remaining 10 (37.0%) patients did not see the dentist look at the MDAS form either because it was not handed over or because it was removed from their line of view. To investigate whether the patient's perception of the dentist looking at their MDAS score, had any influence on patient state and trait dental anxiety, Heart Rate, STAI-S and MDAS mean change scores will be compared. This will be done in relation to three distinct groups: those in the experimental group who saw their dentist look at the MDAS form (the 'Perceived Experimental Group'); those who did not see the dentist look at their MDAS form (the 'Not Perceived Experimental Group') and the Control Group.

Mean change scores for each group were compared using an independent t-test. This was done once Levene's test for equality of variances could be satisfied (P>0.05). In cases where the F statistic was significant Welch's test was used.

Table 39, highlights Comparison Four, where the mean dental anxiety change scores (Heart Rate, STAI-S and MDAS) of patients who saw their dentist look at the MDAS form (Perceived Experimental Group) are compared to those who did not (Not Perceived Experimental Group). Each of the experimental groups (Perceived and Not Perceived) will also be compared to the Control Group. These will be detailed in Comparison Five (Table 40) and Comparison Six (Table 41) respectively.

Table 39: Comparison Four: Mean Change Scores in Experimental Perceived and Not Perceived Groups

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Perceived N=17	7.47 (11.59)	-9-30	2.00-12.93	-0.20 (25)	0.84
	Not Perceived N=10	8.50 (14.84)	-7-45	-0.70-17.70		
STAI-S	Perceived N=17	2.71 (3.93)	-3-11	0.84-4.58	0.12 (25)	0.91
	Not Perceived N=10	2.50 (5.23)	-5-11	-0.74-5.74		
MDAS	Perceived N=17	3.59(4.02)	-4-14	1.68-5.50	-0.05 (25)	0.96
	Not Perceived N=10	3.70 (6.63)	-8-17	-0.41-7.81		

Positive scores indicate a reduction in dental anxiety

Table 40: Comparison Five: Mean Change Scores in Experimental Perceived and Control Groups

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Perceived N=17	7.47 (11.59)	-9-30	2.00-12.93	0.76 (41)	0.45
	Control N=26	4.00 (16.38)	-31-33	-2.30-10.30		
STAI-S	Perceived N=17	2.71 (3.93)	-3-11	0.84-4.58	0.15 (41)	0.88
	Control N=26	2.54 (3.38)	-7-9	-0.01-5.09		
MDAS	Perceived N=17	3.59(4.02)	-4-14	1.68-5.50	-1.12(41)	0.27
	Control N=26	5.08 (4.43)	-1-13	3.38-6.78		

Positive scores indicate a reduction in dental anxiety

Table 41: Comparison Six: Mean Change Scores in Experimental Not Perceived and Control Groups

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Not Perceived N=10	8.50 (14.84)	-7-45	-0.70-17.70	-0.72(34)	0.47
	Control N=26	4.00 (16.38)	-31-33	-2.30-10.30		
STAI-S	Not Perceived N=10	2.50 (5.23)	-5-11	-0.74-5.74	-0.02(12.02)*	0.98
	Control N=26	2.54 (3.38)	-7-9	-0.01-5.09		
MDAS	Not Perceived N=10	3.70 (6.63)	-8-17	-0.41-7.81	-0.28 (32)	0.75
	Control N=26	5.08 (4.43)	-1-13	3.38-6.78		

Positive scores indicate a reduction in dental anxiety

*Welch's test used as equal variance could not be assumed (F=0.04).

In relation to Comparison Four, the Experimental Perceived Group and the Experimental Not Perceived Group, no statistically significant variation in mean change score for dental anxiety was observed (Heart Rate: -1.03; 95% CI -11.54 to 9.48; *P*>0.05); (STAI-S: 0.21; 95% CI -3.44 to 3.85; *P*>0.05); (MDAS Comparison Four: -0.11; 95% CI -4.31 to 4.09; *P*>0.05). This result was consistent with Comparison Five, where the Experimental Perceived Group was compared to the control (Heart Rate: 3.47; 95% CI -5.77 to 12.71; *P*>0.05); (STAI-S: 0.17; 95% CI -2.10 to 2.44; *P*>0.05); (MDAS: -1.49; 95% CI -4.18 to 1.20; *P*>0.05). Comparison Six, the Experimental Not Perceived Group and the control also highlighted no significant statistical difference (Heart Rate: 4.50; 95% CI -7.59 to 16.59; *P*>0.05); (STAI-S: -0.04; 95% CI -3.92 to 3.84; *P*>0.05); (MDAS: -1.38; 95% CI -5.23to 2.48; *P*>0.05).

In other words, the three groups (Experimental Perceived, Experimental Not Perceived and Control) appear to be similar in terms of state and trait dental anxiety mean change scores.

5.3.4(v) Qualitative Vignettes: Patient Perceived Dentist Behaviour

To provide more breadth and depth to the patients' perceived dentist behaviour within the experimental group, qualitative vignettes were used. Within the Perceived Experimental Group, vignettes appeared to focus around the key theme of 'reassurance'; provided by the dentist, the patient or in some cases both individuals.

Examples of Perceived Experimental Group Vignettes: Reassurance by Dentist

Vignettes L, M, and N, highlight dentist initiated reassurance, where the dentist makes sure that the patient is aware that they have read the MDAS form. Dentists appear to do this in two ways, either by standing directly in front of the patient to read the form (Vignettes L, and M) or by sitting alongside the patient (Vignette N).

Vignette L: *Dental team greet patient. Patient enters surgery and hands over MDAS form immediately. Patient sits down on dental chair after placing bag on nearby chair. Dentist reads MDAS form directly in front of patient. Patient appears distracted. Dentist continues to look at MDAS as walks over to close surgery door. Patient briefly looks up to see dentist looking at MDAS form. Dentist walks back to chair holding MDAS and engages patient.*

Vignette M: *Patient enters surgery with MDAS form. The dentist waits at doorway for patient to welcome him. Patient hands over MDAS form to dentist. Patient then proceeds to take coat off and place it on the chair. Dentist engages patient as looks at MDAS form. Patient sees dentist looking at form. Patient moves to sit down on dental chair as continues to engage dentist in conversation. Dentist moves towards computer but continues to look at MDAS form.*

Vignette N: *Patient enters surgery with MDAS form. Patient clasps stomach. Dentist walks over to meet patient at the door. Patient hands over MDAS form. Patient stands at doorway near foot of dental chair, looking at dental chair. Dentist invites patient to sit in dental chair. Dentist looks at MDAS form. Dentist draws over seat to sit next to patient as reads form.*

Examples of Perceived Experimental Group Vignettes: Reassurance by Patient

In some cases reassurance was initiated by the patient. Here the patient made sure that they saw the dentist read their MDAS form. This was done either by presenting the form in a way that the dentist could not dismiss (Vignette O) or by turning around in the dental chair to reassure themselves that the form was actually being read by the dentist (Vignette P).

Vignette O: *Dentist waits at door for patient. Dentist welcomes patient. Patient enters dental surgery holding MDAS form at arm's length with printed side facing dentist. Patient presents form to dentist. Dentist thanks patient and looks at form.*

Vignette P: *The dentist engages the patient and takes the form from her. The dentist immediately places the form on the work surface as she is in the middle of washing her hands. Dentist invites patient to sit in the dental chair. Patient walks over to dental chair and sits down. Patient fidgets with neck scarf. Dental nurse engages patient. Dentist looks at MDAS form behind patient. Patient turns around to see dentist studying form. Patient smiles and continues to engage with dental nurse.*

Examples of Perceived Experimental Group Vignettes: Reassurance by Both

Reassurance, in some cases was demonstrated by both dentist and patient. Here while the dentist made sure that the patient saw them read the MDAS form, the patient reinforced form reading by directing the dentist back to the text (Vignettes Q and R).

Vignette Q: *Dentist meets patient at door, greets and invites patient to sit in dental chair. Patient walks into surgery with MDAS form and walks over to chair to put down her coat and handbag. Dentist engages patient while patient hands over MDAS form. Patient walks over to dental chair and sits down as dentist stands in front of chair looking at MDAS form. Patient points to MDAS form and engages dentist regarding its contents. Dentist acknowledges this then places form on chair next to patient's coat.*

Vignette R: *Patient hands over MDAS form to dentist. Dentist stands facing patient as reads form. Patient places hand on her stomach and expresses her anxiety regarding seeing dental chair, then laughs.*

Examples of Not Perceived Experimental Group Vignettes

In relation to the Not Perceived Experimental Group, two key themes appeared within the vignettes: either the MDAS form was forgotten (Vignette S) or it was removed from the patient's line of sight (Vignette T)

Vignette S: *Patient enters surgery, Dentist walks over to greet patient. Patient hands over the MDAS form to the Dentist. Dentist notices some water on the dental chair immediately puts form down without looking at it and reaches for some paper towels to dry the dental chair. Dentist then invites patient to sit down. Dentist introduces herself and explains the nature of today's appointment.*

Vignette T: *Patient enters surgery with MDAS form and immediately hands over the form to the dentist. Dentist greets patient and escorts her over to chair to lay down shopping bags. As patient puts down bags, dentist looks at the MDAS form. Patient's back is towards dentist. Dentist takes form and places it onto unit work surface. Dentist walks back to patient (still standing with back towards dentist) and helps patient out of coat then directs her to the dental chair.*

5.3.4(vi) Quantitative Analysis: Actual Dentist Behaviour

This section investigates the effect of actual dentist behaviour (in relation to the reading of the MDAS form) on patient state and trait dental anxiety. In total, the dentist looked at the MDAS text in 22 (81.5%) of the 27 experimental cases. This occurred primarily within the first two minutes of each dental appointment. Additional form reading occurred in four of the 22 cases, two at the very end of the appointment just before the form handed back to the patient, once following administration of local anaesthetic (LA), and once just before LA administration.

The dentist held onto the MDAS form for an average of 21.86 seconds (SD 18.93), with the form being put down and picked up between one and two times. On average the MDAS form text was viewed by the dentist for 8.68 seconds (SD 7.13) within the first two minutes of the dental appointment, with dentists viewing the form between one and four times.

To consider whether the dentist reading the MDAS form had any effect on patient dental anxiety, the experimental group was divided according to whether the dentist read the MDAS form (Read Experimental Group) or did not (Unread Experimental Group). In Comparison Seven, both these groups were compared (see Table 42), while in Comparison Eight (Table 43) and Nine (Table 44), each experimental group (Read and Unread) was compared with the Control Group.

The mean change scores for both state and trait dental anxiety measurements were again investigated and an independent t-test was undertaken, once Levene's test for equality of variances had been satisfied for each variable ($P>0.05$).

Table 42: Comparison Seven: Mean Change Scores in Experimental Read and Unread Groups

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Read N=22	8.45 (13.55)	-9-45	2.79-14.11	0.51 (25)	0.61
	Unread N=5	5.20 (7.12)	-7-10	-1.04-11.44		
STAI-S	Read N=22	2.45 (4.19)	-5-11	0.70-4.20	-0.43 (25)	0.67
	Unread N=5	3.40 (5.50)	-4-11	-1.42-8.22		
MDAS	Read N=22	3.18 (3.86)	-4-14	1.57-4.79	-0.97 (25)	0.34
	Unread N=5	5.60 (8.90)	-8-17	-2.15-13.46		

Positive scores indicate a reduction in dental anxiety

Table 43: Comparison Eight: Mean Change Scores in Experimental Read and Control Groups

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Read N=22	8.45 (13.55)	-9-45	2.79-14.11	1.01 (46)	0.32
	Control N=26	4.00 (16.38)	-31-33	-2.30-10.30		
STAI-S	Read N=22	2.45 (4.19)	-5-11	0.70-4.20	-0.08 (46)	0.94
	Control N=26	2.54 (3.38)	-7-9	-0.01-5.09		
MDAS	Read N=22	3.18 (3.86)	-4-14	1.57-4.79	-1.57 (46)	0.12
	Control N=26	5.08 (4.43)	-1-13	3.38-6.78		

Positive scores indicate a reduction in dental anxiety

Table 44: Comparison Nine: Mean Change Scores in Experimental Unread and Control Groups

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Unread N=5	5.20 (7.12)	-7-10	-1.04-11.44	0.16 (29)	0.87
	Control N=26	4.00 (16.38)	-31-33	-2.30-10.30		
STAI-S	Unread N=5	3.40 (5.50)	-4-11	-1.42-8.22	0.47 (29)	0.64
	Control N=26	2.54 (3.38)	-7-9	-0.01-5.09		
MDAS	Unread N=5	5.60 (8.90)	-8-17	-2.15-13.46	0.20 (29)	0.84
	Control N=26	5.08 (4.43)	-1-13	3.38-6.78		

Positive scores indicate a reduction in dental anxiety

In relation to Comparison Seven where the Experimental Read Group are compared to the Experimental Unread Group, no statistically significant variation in dental anxiety mean change score was reported (Heart Rate: 3.25; 95% CI -9.75 to 16.26; *P*>0.05); (STAI-S: -0.94; 95% CI -5.46 to 3.57; *P*>0.05) (MDAS: -2.42; 95% CI -7.54 to 2.70; *P*>0.05). In Comparison Eight, the Experimental Read Group compared to the Control, also highlighted no statistically significant difference (Heart Rate: 4.45; 95% CI 4.38 to 13.29; *P*>0.05); (STAI-S: -0.08; 95% CI -2.28 to 2.12; *P*>0.05); (MDAS: -1.89; 95% CI -4.33 to 0.54; *P*>0.05). Finally, in relation to Comparison Nine, no statistically significant result was found (Heart Rate: 1.20; 95% CI -14.22 to 16.62; *P*>0.05); (STAI-S: 0.86; 95% CI -2.88 to 4.61; *P*>0.05); (MDAS: 0.52; 95% CI -4.74 to 5.79; *P*>0.05). In other words, the three groups (Experimental Read, Experimental Unread and control) appear to be similar in terms of state and trait dental anxiety mean change scores.

5.3.4(vii) Qualitative Vignettes: Actual Dentist Behaviour

To consider the complexity and diversity of dentist behaviour, vignettes from both the Experimental Read and Unread Groups were considered. Key themes were teased out to provide a contextual framework to the qualitative aspect of the actual dentist behaviour analysis.

Within the Experimental Unread Group, the vignettes echo the various reasons for the dentist not receiving the MDAS form (see Vignettes E,G and I) as well as being distracted from going on to read it (Vignette S).

Examples of Read Experimental Group Vignettes: MDAS Uncertainty

In the Experimental Read Group, the vignettes highlight a variation in MDAS form use. One of the key vignette themes relates the uncertainty expressed by dentists relating to how the MDAS information should be used.

Vignette U: *Dentist extends hand towards form but then withdraws it. Dentist continues to look in direction of MDAS form. Patient sits in dental chair. Dentist again turns to look in direction of form [on unit]. Dental nurse engages patient. Dentist stands up and moves towards MDAS form. Dentist picks up form, glances at printed side then turns it over, turns it back and places it back onto work surface.*

Vignette V: *Dentist looks at form and asks patient if it is for him. Patient says it is. Dentist folds to close form but immediately opens it again. Patient takes coat off and jokes with dentist regarding form contents.*

Dentist laughs and folds the form again while showing patient where to hang coat. Dental nurse engages with dentist and dentist yet again opens form to glance at it. Dentist asks patient whether the form should be kept by the patient. Patient replies that he was told to give the form to the dentist. Dentist looks a little confused and turns to place the form on the work surface. Both patient and dentist laugh. The dentist invites the patient to sit down in the dental chair.

Examples of Read Experimental Group Vignettes: MDAS Prompt Use

In the minimal of cases (n=2) the dentist uses the MDAS form as a prompt for further anxiety discussion as highlighted in Vignette W.

Vignette W: *Dentist invites patient to sit in dental chair. Dentist looks at MDAS form. Dentist draws over seat to sit next to patient as reads form. Dentist reads aloud patient answers, patient laughs. Both dentist and patient laugh. Dentist reassures patient and places MDAS form on unit work surface. Dentist continues to engage patient regarding how she feels about dentistry. Patient laughs. Both patient and dentist laugh together. Dentist reassures patient regarding today's treatment. Patient stops clenching stomach. Dentist continues to engage patient.*

Examples of Read Experimental Group Vignettes: MDAS Dismissal

Most vignettes however demonstrate a dismissal of the form, putting it aside at the initial stages of the dental appointment as highlighted in Vignettes X and Y.

Vignette X: *Patient enters surgery holding form. Dentist greets patient. Patient responds and walks towards dentist who is standing next to unit work surface. Patient hands over MDAS form. Dentist thanks patient and places in onto work surface. Patient informs dentist of problems with prescribed antibiotics. Dentist picks up MDAS form and invites patient to sit in dental chair. Patient sits down on chair as dentist walks back to unit and looks at MDAS form. Patient turns to see dentist looking at form as dentist asks patient if form is from researcher. Dentist acknowledges it is, puts form down and checks patient notes on the computer while asking patient about antibiotics. Dentist then moves towards patient and stands next to dental chair while discussing patient's reason for attendance. Dentist moves towards dental unit to put on gloves and check computer notes. Dentist engages with patient as looks at computer screen.*

Vignette Y: *Patient enters surgery with MDAS form. Dentist seated greets patient as patient hands over MDAS form. Patient walks over to chair and places coat and handbag down. Dentist prepares dental chair and invites patient to sit down. As patient sits down in chair dentist engages her while reading the MDAS form. Patient does not see the dentist look at form as out of line of sight. Dentist engages patient again and folds MDAS form then places it onto the work surface.*

5.3.5 Emotion Cues & Concerns Study Results

In the second observational element of Study Two, the affective aspect of the dentist-patient interaction is investigated. Post-treatment outcome measures for dental state anxiety (Heart Rate and STAI-S) and dental trait anxiety (MDAS) were considered in relation to the observed emotional content expressed within the healthcare dyad.

The Verona Coding system is used in this investigation and provides dyadic assessment of both verbal and non-verbal emotional elements. This analysis focuses on the two minute framework established by the behavioural analysis, associated with MDAS handover.

As already established, there were 51 recordings suitable for coding using the Verona CoDES system. Any missing values were addressed by averaging the total value within the surgery's control group, and substituting missing data with appropriate average replacement values. A sensitivity analysis was also completed in addition using only completed data sets.

Quantitative analysis relating to frequency of coded emotional cues and concerns was supplemented by qualitative vignettes highlighting various emotional dyadic themes.

The affective aspects of the patient-dentist dyad will now be unpacked to examine the emotional content expressed by both patient and dentist in relation to MDAS handover activity.

A tentative hypothesis was formulated. The patients in the experimental group were able to express their concern about dental anxiety in the handover of the MDAS to the dentist.

The expectation would be for the initial interaction between the patient and dentist to contain a number of references to concerns and emotional cues in the experimental group which would be of a greater frequency than in the control group. In addition the dentist may be able to respond to the patients' expression of emotion by providing some space to discuss their anxiety and to do this explicitly.

Hence the hypothesis that could be proposed would be that experimental group patients will express a higher level of concerns and cues compared to the control group patients. Likewise the number of explicit and providing space responses by dentists will be greater in the experimental group compared with the control group.

5.3.5(i) Quantitative Analysis: Expressed Patient Emotion

In an attempt to communicate their perceived dental anxiety to the dentist and dental team, a patient can elicit emotional cues and concerns. The patient may be very clear in their expression of dental anxiety, explicitly verbalising their apprehension e.g. "I am worried about ..." or "I am nervous". In this case according to the Verona coding system this would be classified as a 'concern'.

An example of this is clearly seen in the following vignette:

Vignette (i): *Dentist: How are you today?*

Patient: I am scared! [CONCERN]

Dentist: {silence}

Patient: Can I have a wee drink of water please?

If however the patient hints towards their emotional status either verbally or non-verbally, this can be classified as a 'cue'.

Vignette (ii): *Dentist: How are you doing today?*

Patient: {sarcastic tone} Fine thank you, I couldn't wait to get here!

[CUE]

Dentist: {laughs}

The expression of cues and concerns will now be considered first in relation to whether the patient was part of the experimental group (instructed to give their MDAS form to the dentist) or the control group, and secondly in relation to dental state and trait anxiety.

- **Expression of Cues and Concerns in Relation to Randomised Group**

In total, a similar number of cues and concerns were expressed between both control and experimental groups; 55 cues and concerns were communicated by patients in the control group while 49 cues and concerns were expressed in the experimental group. Of those patients expressing emotion within the dyad, 24 (45.3%) only used cues while three patients (5.7%) used only concerns, seven (13.2%) patients used both means to express how they felt while 19 (35.8%) patients did not express emotion in the form of cues and concerns as classified by the Verona CoDES system. The coding was completed in discussion with GH to ensure that the coding was accurate.

The duration of expressed cues and concerns was also investigated. Table 45 highlights the mean duration of patient expressed emotion in relation to each randomised group. An independent t-test highlights no statistically significant difference between values (Levene's Test for equality of variances; F>0.05; *P*>0.05).

Table 45: Mean Cue and Concern Duration in Experimental and Control Groups

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
Cue Duration (Seconds)	Experimental N=27	4.00 (6.67)	0-25	1.48-6.51	0.97(51)	0.33
	Control N=26	5.99(8.21)	0-34	2.84-9.14		
Concern Duration (Seconds)	Experimental N=27	0.63 (1.82)	0-8	-2.02-3.28	0.06 (51)	0.95
	Control N=26	0.66(1.69)	0-7	0.01-1.31		

The mean duration difference of cues (1.99 seconds; 95% CI -2.12 to 6.11; *P*>0.05) and concerns (0.03 seconds; 95% CI -0.94 to 1.00; *P*>0.05) was comparable in both control and experimental groups, with no statistically significant difference.

- **Expression of Cues and Concerns in Relation to Dental Anxiety**

Cues and concerns were also analysed in relation to study outcome i.e. dental trait and state anxiety. Table 46 demonstrates the relationship between dental anxiety and individual patient expressed emotion.

Table 46: Mean Dental Anxiety Change Scores in Relation to Expressed Patient Cues and No Expressed Emotion.

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Cue N=24	7.87 (15.27)	-31-33	1.66-14.08	-0.05 (41)	0.96
	None N=19	8.10 (13.38)	-9-45	2.08-14.12		
STAI-S	Cue N=24	2.58 (4.15)	-5-11	0.91-4.25	-0.60 (41)	0.55
	None N=19	3.26 (3.02)	0-11	1.90-4.86		
MDAS	Cue N=24	3.21 (3.84)	-4-14	1.68-4.74	-2.27 (41)	0.03
	None N=19	6.10 (4.51)	-1-17	4.07-8.13		

Positive scores indicate a reduction in dental anxiety

Table 47: Mean Dental Anxiety Change Scores in Relation to Expressed Patient Concerns and No Expressed Emotion

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Concern N=3	-14.67 (8.96)	-25--9	-24.80- -4.54	-2.82 (20)	0.01
	None N=19	8.10 (13.38)	-9-45	2.08-14.12		
STAI-S	Concern N=3	-1.67(5.51)	-7-4	-7.90-4.56	-2.37(20)	0.03
	None N=19	3.26 (3.02)	0-11	1.90-4.86		
MDAS	Concern N=3	1.67 (2.08)	0-4	-0.68-4.02	-1.65 (20)	0.11
	None N=19	6.10 (4.51)	-1-17	4.07-8.13		

Positive scores indicate a reduction in dental anxiety

Table 48: Mean Dental Anxiety Change Scores in Relation to Expressed Patient Cues and Concerns (Both) and No Expressed Emotion

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Both N=7	2.42 (11.00)	-21-14	-5.73-10.57	-1.00 (24)	0.33
	None N=19	8.10 (13.38)	-9-45	2.08-14.12		
STAI-S	Both N=7	2.57 (4.04)	-4-9	-0.42-5.56	-0.47(24)	0.64
	None N=19	3.26 (3.02)	0-11	1.90-4.86		
MDAS	Both N=7	4.57 (7.59)	-8-13	1.06-10.19	-0.64 (24)	0.53
	None N=19	6.10 (4.51)	-1-17	4.07-8.13		

Positive scores indicate a reduction in dental anxiety

Table 47 highlights the relationship between expressed patient cues and dental trait and state anxiety. In this comparison those patients who did not express any emotion experienced a statistically significant fall in dental trait anxiety, (MDAS: -2.90; 95% CI -5.47 to -0.32; *P*=0.028) compared to those who did; however in relation to dental state anxiety (both physiological and emotional) no significant difference was observed (Heart Rate: -0.23; 95% CI -8.81 to 8.66; *P*>0.05); (STAI-S: -0.68; 95% CI -2.97 to 1.61; *P*>0. 05).

In cases where patients expressed their emotion via concerns (Table 48), a statistically significant increase in both dental state anxiety measures was observed (Heart Rate: -22.77; 95% CI -39.63 to -5.91; *P*=0.011); (STAI-S: -4.93; 95% CI -9.27 to -0.59; *P*=0.028), while no difference was exhibited in dental trait anxiety (MDAS: -4.44; 95% CI -10.05 to 1.17; *P*>0.05).

When both cues and concerns were expressed by patients no statistically significant difference in mean change scores was exhibited (Heart Rate: -5.67; 95% CI -17.38 to 6.03; *P*>0.05); (STAI-S: -0.69; 95% CI-3.70 to 2.32; *P*>0.05); (MDAS: -1.53; 95% CI -6.50 to 3.43; *P*>0.05).

5.3.5(ii) Quantitative Analysis: Dentist Response to Patient Emotion

In the Verona coding system, each expression of patient emotion sits in direct relationship with the health professional's response. In other words, patient cues and concerns are not independent, but exist within a healthcare communication couplet.

The dentist's response is therefore intrinsically linked to the patient's expressed emotion. In relation to the Verona CoDES, responses can be coded using two main categories: either as 'explicit' responses where there is a specific mention of the patient's expressed emotion e.g. "so you feel anxious...?" or a 'non-explicit' response where the emotional content originally expressed by the patient is not mentioned by dentist e.g. "Oh poor you!"

Vignette (iii) highlights an explicit response provided by the dentist while Vignette (iv) provides an example of a non-explicit reply.

Vignette (iii):

Patient: Did they warn you?

Dentist: What? About you being nervous?

} Couplet

Patient: {laughs with Dentist}

Vignette (iv): *Dentist: How are you today?*

Couplet { *Patient: Not that great actually...*

Dentist: Are you not? What's wrong?

Each of these main categories can in turn be divided into two subgroups; those where the response provided by the dentist is said to 'reduce space' (closes down further disclosure from the patient) or 'provide space' (encourages further patient discussion in relation to their cue or concern).

An example of a 'provide space' response is highlighted in Vignette (v) while Vignette (vi) demonstrates how a dentist closes down the anxiety discussion.

Vignette (v): *Dentist: How are you?*

Couplet { *Patient: I am very nervous!*

Dentist: You're nervous?

Vignette (vi): *Patient: I knew that as soon as I saw that chair that would be it....*

Dentist: Have a seat.

In this section, the dentist's response will be analysed first in relation to group randomisation, and secondly in relation to dental state and trait anxiety.

- **Dentist Response to Patient Emotion in Relation to Randomisation**

Patient-dentist communication relating to dental anxiety, occurred in 64% (n=34) of the videoed dental treatment appointments. Within these interactions dentists elicited a total of 104 individual responses, with 93 (89.4%) being non-explicit and 11 (10.6%) explicit. Similar numbers of non-explicit and explicit responses were expressed between both control and experimental group dentists; 48 non-explicit and seven explicit responses were communicated in the control group while 45 non-explicit and four explicit responses were expressed in the experimental group.

Of the 34 cases where emotional communication occurred, dentists used exclusively non-explicit responses in 26 (76.5%) interactions, both explicit and non-explicit responses in seven (20.6%) interactions and exclusively explicit responses in only one (2.9%) interaction.

In relation to the Verona system subgroups, 72 (69.2%) of the 104 responses elicited by dentists were categorised as 'reduce-space' while only 32 (30.8%) were said to 'provide space' for patient discussion. In the majority of interactions (19, 55.9%), dentists used a combination of both 'provide-space' and 'reduce space' responses. The 'reduce space' response was used exclusively in 13 (38.2%) of the 34 interactions while in only two (5.9%) cases the 'provide-space' response was exclusively used.

To consider the dentist response in more detail, the mean frequencies of each of the four individual response types are highlighted in Table 49.

The independent t-test shows no statistically significant mean difference between experimental and control groups in relation to dentist response type (Explicit Provides Space: 0.04; 95% CI -0.24 to 0.33; *P*>0.05); (Explicit Reduces Space: 0.08; 95% CI-0.03 to 0.19; *P*>0.05); (Non-Explicit Provides Space: 0.05; 95% CI -0.30 to 0.41; *P*>0.05); (Non-Explicit Reduces Space: 0.12; 95% CI -0.81 to 1.06; *P*>0.05).

In other words the composition of the dental dyad in relation to dentist response was similar in both experimental and control groups.

Table 49: Mean Dentist Response Frequencies: Experimental and Control Groups

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
Explicit Space	Experimental N=27	0.15 (0.60)	0-3	-0.08-0.38	0.31(51)	0.76
	Control N=26	0.19 (0.40)	0-1	0.03-0.34		
Explicit Reduce Space	Experimental N=27	0.00 (0.00)	0	0	1.44(25)*	0.16
	Control N=26	0.08 (0.27)	0-1	-0.02-0.18		
Non-Explicit Space	Experimental N=27	0.41 (0.64)	0-2	0.17-0.65	0.31(51)	0.76
	Control N=26	0.46 (0.65)	0-2	0.21-0.71		
Non-Explicit Reduce Space	Experimental N=27	1.26 (1.51)	0-5	0.69-1.83	0.27(51)	0.79
	Control N=26	1.38 (1.88)	0-7	0.66-2.10		

*Welch's test used as equal variance could not be assumed (F=0.002).

- **Patient Dental Anxiety in relation to Dentist Response Type**

Dentist response will now be analysed in relation to study outcome i.e. dental trait and state anxiety. Before effects of the types of dentist response are analysed, the effect of dental anxiety 'discussion' (i.e. any dental anxiety interchange coded by the Verona System:- patient cue or concern accompanied by a dentist response) will be considered in relation to patient dental anxiety outcome measures (see Table 50).

Table 50: Mean Dental Anxiety Change Scores in Relation to Dental Anxiety 'Discussion'

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Anxiety Discussion N=34	4.76 (15.23)	-31-33	-0.36-9.88	-0.80 (51)	0.43
	None N=19	8.10 (13.38)	-9-45	2.08-14.12		
STAI-S	Anxiety Discussion N=34	2.21 (4.38)	-7-11	0.77-3.65	-0.95(51)	0.35
	None N=19	3.26 (3.02)	0-11	1.90-4.86		
MDAS	Anxiety Discussion N=34	3.35 (4.65)	-8-14	1.79-4.91	-2.01 (51)	0.04
	None N=19	6.10 (4.51)	-1-17	4.07-8.13		

Positive scores indicate a reduction in dental anxiety

Following the validation of the independent t-test (F>0.05), the results of the analysis indicate a statistically significant reduction in dental trait anxiety within the group of patients who did not 'discuss' their anxiety with the dentist (-2.75; 95% CI -5.40 to 0.11; *P*=0.042). No other statistically significant result was identified (Heart Rate: -3.34; 95% CI -11.74 to 5.06; *P*>0.05); (STAI-S: -1.06; 95% CI-3.29 to 1.17; *P*>0.05)

In relation to non-explicit and explicit dentist elicited responses, no statistically significant result was shown (Tables 51 and 52). This was echoed in relation to the subgroup coding of 'provide-space' (highlighted in Table 53), however in cases where space for emotional 'discussion' was reduced, a statistically significant result in relation to trait dental anxiety was observed (Table 54).

Table 51: Mean Dental Anxiety Change Scores in Relation to Non-Explicit Dentist Response.

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Non-Explicit N=33	5.67 (14.51)	-31-33	0.71-10.63	-0.19 (51)	0.85
	Other N=20	6.45 (14.98)	-25-45	0.12-13.02		
STAI-S	Non-Explicit N=33	2.15 (4.33)	-7-11	0.67-3.63	-1.05 (51)	0.30
	Other N=20	3.30 (2.94)	0-11	2.01-4.59		
MDAS	Non-Explicit N=33	3.42 (4.70)	-8-14	1.81-5.03	-1.84 (51)	0.07
	Other N=20	5.85 (4.53)	-1-17	3.86-7.84		

Positive scores indicate a reduction in dental anxiety

Table 52: Mean Dental Anxiety Change Scores in Relation to Explicit Response.

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Explicit N=9	1.56 (19.38)	-25-29	-11.10-14.22	-1.00 (51)	0.32
	Other N=44	6.86 (13.46)	-31-45	2.88-10.84		
STAI-S	Explicit N=9	1.78 (4.55)	-7-9	-1.20-4.76	-0.68 (51)	0.50
	Other N=44	2.75 (3.76)	-5-11	1.63-3.87		
MDAS	Explicit N=9	4.22 (5.26)	0-13	0.79-7.65	-0.08 (51)	0.94
	Other N=44	4.36 (4.71)	-8-17	2.97-5.75		

Positive scores indicate a reduction in dental anxiety

Table 53: Mean Dental Anxiety Change Scores in Relation to 'Provide Space' Response.

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Provide Space N=21	2.67 (15.50)	-31-27	-03.96-9.30	-1.35 (51)	0.18
	Other N=32	8.12 (13.71)	-14-45	3.37-12.87		
STAI-S	Provide Space N=21	2.05 (4.20)	-7-10	0.25-3.85	-0.81 (51)	0.42
	Other N=32	2.94 (3.67)	-4-11	1.67-4.21		
MDAS	Provide Space N=21	4.43 (3.94)	0-13	2.74-6.12	-0.12 (51)	0.91
	Other N=32	4.28 (5.27)	-8-17	2.46-6.10		

Positive scores indicate a reduction in dental anxiety

Table 54: Mean Dental Anxiety Change Scores in Relation to 'Reduce Space' Response.

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Reduce Space N=32	5.34 (15.46)	-31-33	-0.02-10.70	-0.38 (51)	0.71
	Other N=21	6.90 (13.36)	-10-45	1.18-12.62		
STAI-S	Reduce Space N=32	2.53 (4.07)	-5-11	1.12-3.94	-0.12 (51)	0.90
	Other N=21	2.67 (3.65)	-7-11	1.11-4.23		
MDAS	Reduce Space N=32	3.22 (4.75)	-8-14	1.57-4.87	-2.12 (51)	0.03
	Other N=21	6.05 (4.31)	-1-17	4.21-7.89		

Positive scores indicate a reduction in dental anxiety

This result can be further investigated by considering the dentists' use of the reduce-space response. In 36% (n=19) of cases the dentist used both 'reduce space' and 'provide space' responses, dentists only used provide space in 4% (n=2), while reduce space was exclusively used in 24% (n=13) of interactions. In 36% (n=19) of cases no anxiety 'discussion' was coded by the Verona System.

Tables 55, 56 and 57 highlight the relationship between dental trait and state anxiety, in relation to the response combination used by the dentist. Each response combination is compared to the group where no anxiety 'discussion' occurred.

Table 55: Mean Dental Anxiety Change Scores in Relation to Exclusive use of 'Reduce Space' Response by Dentist.

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Reduce Space Only N=13	8.15 (14.74)	-14-33	0.13-16.17	0.10 (30)	0.99
	None N=19	8.10 (13.38)	-9-45	2.08-14.12		
STAI-S	Reduce Space Only N=13	2.46 (4.56)	-4-11	-0.01-4.93	-0.56 (19.12)*	0.58
	None N=19	8.10 (13.38)	-9-45	2.08-14.12		
MDAS	Reduce Space Only N=13	1.61 (5.32)	-8-14	-1.27-4.49	-2.57 (30)	0.01
	None N=19	6.10(4.51)	-1-17	4.08-8.12		

Positive scores indicate a reduction in dental anxiety

*Welch's test used as equal variance could not be assumed (F=0.002).

Table 56: Mean Dental Anxiety Change Scores in Relation to Exclusive use of 'Provide Space' Response by Dentist.

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Provide Space Only N=2	-4.50 (7.78)	-10-1	-15.28-6.28	-1.29 (19)	0.21
	None N=19	8.10 (13.38)	-9-45	2.08-14.12		
STAI-S	Provide Space Only N=2	-3.00 (5.66)	-7-1	-10.84-4.84	-2.62 (19)	0.02
	None N=19	8.10 (13.38)	-9-45	2.08-14.12		
MDAS	Provide Space Only N=2	5.50 (2.12)	4-7	2.56-8.44	-0.18 (19)	0.86
	None N=19	6.10(4.51)	-1-17	4.08-8.12		

Positive scores indicate a reduction in dental anxiety

Table 57: Mean Dental Anxiety Change Scores in Relation to use of both 'Reduce Space' and 'Provide Space' Responses by Dentist.

		Mean (SD)	**Range**	**CI 95%**	**t(df)**	**P**
HR	Both N=19	3.42 (16.04)	-31-27	-3.79-10.63	-0.98 (36)	0.33
	None N=19	8.10 (13.38)	-9-45	2.08-14.12		
STAI-S	Both N=19	2.58 (3.83)	-5-10	0.86-4.30	-0.61 (36)	0.54
	None N=19	8.10 (13.38)	-9-45	2.08-14.12		
MDAS	Both N=19	4.32 (4.11)	0-13	2.48-6.16	-1.28 (36)	0.21
	None N=19	6.10(4.51)	-1-17	4.08-8.12		

Positive scores indicate a reduction in dental anxiety

Exclusive use of 'provide space' highlighted a statistically significant increase in patient emotional dental state anxiety (STAI-S: -6.26; 95% CI -11.26 to -1.27; *P*=0.017) while the exclusive use of 'reduce space' responses had a longer term effect on the patient's trait dental anxiety reduction (MDAS: -4.49; 95% CI -8.05 to -0.93; *P*=0.015). Use of both 'reduce space' and 'provide space' responses by the dentist did not have a statistically significant effect on patient trait or state dental anxiety (Heart Rate: -4.68; 95% CI -14.40 to 5.03; *P*>0.05); (STAI-S: -0.68; 95% CI -2.95 to 1.58; *P*>0.05); (MDAS: -1.79; 95% CI -4.63 to 1.05; *P*>0.05).

These quantitative results are further investigated in Section 5.3.6.

5.3.6 Predicting Changes in Dental Anxiety

This section aims to further explore the statistically significant effects reported in Section 5.3.4 (ii) and Section 5.3.5 (ii). The author was aware that there were numerous t-tests performed and no adjustment for any difference in demographic breakdown or dental treatment variables had been made. Therefore, linear modelling was used in this section to determine further the effects of highlighted key independent variables within the healthcare dyad, hypothesized to be instrumental in influencing (a) dental state anxiety (Section 5.3.6(i)) and (b) dental trait anxiety (Section 5.3.6(ii)). Such a statistical approach enables a more careful inspection of hypothesised effects, controlling for other variables deemed not to be central to the main research questions.

5.3.6(i) Predicting Changes in Dental State Anxiety

A hierarchical multiple regression analysis was used to consider the potentially meaningful relationship between change dental state anxiety (the dependant variable where a positive value denotes a reduction over time) and study predictor variables, in particular patient's adherence behaviour to study protocol. The data used were only those patients in the experimental group.

Predictor independent variables were entered into the regression model in a structured two 'block' format.

The first block consisted of demographic independent variables that essentially required controlling for in the regression model (patient age and gender), while the second block contained the variable of interest, i.e. the effect of patient non-adherence with study protocol (Non-Adherence). The analysis is highlighted in Table 58.

The independent variables in Model 1 contribute no significant or meaningful amount of variance, while the addition of the 'Non-Adherence' variable in Model 2 explains 11% (R^2 = 0.11) of the variance shown in patient dental state anxiety. The negative Beta value indicates a negative association between the 'Non-adherence' variable and patient state dental anxiety.

Table 58: Multiple Linear Regression Summary Results of Predicting Change in Dental State Anxiety

		b	SE b	t	P	△F	△P
Model 1	Constant	1.64	1.69	0.97	0.33	0.42	0.66
	Patient Gender	-0.74	1.22	-0.61	0.55		
	Patient Age	0.03	0.04	0.72	0.48		
Model 2	Constant	1.91	1.63	1.18	0.24	5.24	0.03*
	Patient Gender*	-1.12	1.18	-0.94	0.35		
	Patient Age**	0.04	0.04	0.96	0.34		
	Non-Adherence***	-3.35	1.46	-2.30	0.03		

R^2 =0.02 for Model 1: △R^2 =0.09 for Model 2 (P<0.05)*
*Female=0, Male=1
**Patient Age= Continuous variable
***Non-Adherence= 1; Adherence=0

5.3.6(ii) Predicting Changes in Dental Trait Anxiety

In relation to dental trait anxiety a univariate factorial analysis of covariance (see Table 21) was first used to consider the effect of the reduce space response highlighted in Section 5.3.5 (ii) to influence longer term dental anxiety levels. Here the presence of a reduce space response within the first two minutes of the dental appointment was related to a statistically significant reduced effect on attenuating dental trait anxiety (F[155.06]=7.51, P=0.009), even after adjustments for gender, age and number of treatment appointments received within the three month follow-up period. Results are highlighted in Table 59.

Table 59: Mean MDAS Change Scores in relation to the 'Reduce Space' Response.

	Change in Dental Trait Anxiety Scores as Measured by MDAS*			
	Mean**	**SE**	**CI 95%**	**N**
Reduce Space Response	3.25	0.89	1.46-5.05	32
Other Response	7.29	1.17	4.93-9.66	21

*ANCOVA controlling for age, gender, number of appointments (F[155.06]=7.51, P=0.009)
**Positive score denotes reduction in trait MDAS over time

These results were further substantiated using hierarchical multiple regression analysis. The dependent variable was change in MDAS while the predictor variables were grouped into the following blocks: block one consisted of patient gender and age, block two considered the number of appointments received by the patient in the three month period between their treatment and contact by the researcher, and block three included the reducing-space response elicited mainly by the dentist during the first two minutes of the dental treatment appointment. The result of this analysis is highlighted in Table 60.

Once the independent variables in Models 1 and 2 had been essentially controlled for, the complete model (Model 3) demonstrated that the presence of a reduce-space response explained 14% ($R^2 = 0.14$) of the variance shown in dental trait anxiety. This analysis was also undertaken in relation to treatment variables (treatment type, use of local anaesthetic, use of drill) and was shown to have no effect.

Table 60: Multiple Linear Regression Summary Results of Predicting Dental Trait Anxiety

		b	SE b	t	P	△F	△P
Model 1	Constant	2.24	2.04	1.10	0.28	1.02	0.37
	Patient Age	0.04	0.05	0.87	0.39		
	Patient Gender	1.61	1.48	1.09	0.28		
Model 2	Constant	220	2.08	1.06	0.30	0.03	0.86
	Patient Age	0.04	0.05	0.82	0.42		
	Patient Gender	1.66	1.52	1.09	0.28		
	No. Appointments	0.05	0.30	0.17	0.86		
Model 3	Constant	3.77	2.11	1.79	0.08	5.32	0.02*
	Patient Age *	0.04	0.05	0.89	0.38		
	Patient Gender**	1.86	1.46	1.27	0.21		
	No. Appointments***	0.11	0.29	0.37	0.71		
	Reduce Space****	-2.99	1.30	-2.31	0.02		

R^2 =0.04 for Model 1: △R^2 =0.001 for Model 2: △R^2 =0.096 for Model 3 (P<0.05)*
*Female=0, Male=1
**Patient Age= Continuous variable
***No. Appointments= Continuous variable
****Reduce space=0, No Reduce space=1

The negative Beta value highlights a negative association between the use of reduce-space responses and reduction in the change dental trait anxiety (MDAS). In other words, the more a dentist uses a reducing space response, the more a patient's longer term dental anxiety is prevented from falling.

Interestingly, when the analysis was re-run to consider the effect dentists only using 'reduce space' responses, this new model (Model 4) explained 16% ($R^2 = 0.16$) of the variance shown in dental trait anxiety. The effect on is highlighted in Table 61 below.

Table 61: Multiple Linear Regression Summary Results of Predicting Dental Trait Anxiety when only Reduced Space Responses are used by the Dentist

		b	SE b	t	P	△F	△P
Model 4	Constant	-0.61	2.23	-0.27	0.78	7.13	0.01*
	Patient Age*	0.04	0.05	0.75	0.46		
	Patient Gender**	2.23	1.45	1.54	0.13		
	No. Appointments***	0.01	0.29	0.05	0.96		
	Reduce Space****	3.91	1.46	2.67	0.01		

R^2 =0.04 for Model 1: △R^2 =0.001 for Model 2: △R^2 =0.12 for Model 3 (P<0.05)*
*Patient Age= Continuous variable
**Female=0, Male=1
***No. Appointments= Continuous variable
****Reduce space=0, No Reduce space=1

5.3.7 Study Two: Discussion of Behavioural and Affective Aspects

This use of a parallel video record, not only provided a view into the complexity of the dental dyad but also detected the lack of study protocol compliance within the experimental group interactions. This non-compliance was the result of patients either not handing over their MDAS to the dentist or being prevented from doing so by the dental team.

The result of this physical block in information flow within the dyad was shown to significantly affect patients' dental state anxiety, with those not adhering to study protocol experiencing no reduction in STAI-S score. This theme of 'blocking' information flow was also evident within the affective element of the observational study.

When the dentist continually 'reduced-space' so preventing the patient from further discussing their dental anxiety, a significant reduction in the fall of patient dental trait anxiety was experienced irrespective of the number and type of appointments received by the patient (that is the lowering of dental anxiety was not substantial when compared to those where the dentist did *not* 'reduce-space').

In clinical terms both the physical blocking of information and closing of space by the dentist means that dentally anxious patients remain anxious for longer. This in turn may affect treatment choice and re-attendance. The present study highlights the importance of the dentists' response to patient emotional expression particularly with two outcomes. The first is how the patient responds immediately after their appointment; and the second the potential to influence patient response to future appointments, even some months later.

Chapter 6

Discussion

6.0 Discussion

6.1 Introduction

Prior to this mixed methods study, the evidence base for Health Communication in dentistry and its effects on adult dental anxiety as a health outcome, was minimal. To understand the results of this mixed methods study in light of current evidence, this general discussion chapter will consolidate the results of Study One (the randomised cross-over study) and Study Two (the observational element) to provide a summary of main findings and a comparison with published studies. This chapter will also consider the strengths and limitations of using a mixed method design in Primary Dental Care as well as the generalisability and implication of study outcomes. To complete this chapter a discussion of study result dissemination and implementation, followed by recommendations for further research, has also been included. It should be noted that individual study results are discussed in detail at the end of their respective sections in this thesis (see Section 5.2.6 and Section 5.3.7).

6.2 Summary of Main Findings

A total of 54 patients agreed to take part in this mixed methods study, with 47 completing the three month follow-up.

Results of the randomised cross-over study showed no difference in state or trait dental anxiety between experimental and control groups, despite a general trend in the sample group, indicating dental anxiety reduction from baseline.

On further examination of Study One results along with the observational outcomes (Study Two results), dental state anxiety was shown to remain high when dentally anxious patients did not adhere to the study protocol. On consideration of the behavioural vignettes a predominant 'blocking' effect was evident. In many cases patients were prevented from handing over their MDAS to the dentist, either by the nurse stepping in to prevent transfer or by the dentist refusing the form.

This' blocking' effect was also prevalent in the emotional content of the VNVC expressed between dentist and patient. In cases where the patient was unable to contain their dental anxiety (expressing it through cues and concerns in the initial two minutes of the dental appointment) dentists tended to close down the discussion (i.e. 'reduce-space'). Where such 'reduce-space' responses were used consistently, this resulted in a significant lack of decline in dental trait anxiety experienced by the patient.

To establish whether these results were not due simply to chance, both effects were further investigated using hierarchical regression analyses. In cases where non-adherence to study protocol occurred (predominantly blocking of handover behaviour), patients' dental state anxiety remained high even after controlling for both gender and age.

Longer term dental anxiety effects (dental trait anxiety) demonstrated by the consistent use of 'reduce-space' responses, were also shown to occur irrespective of gender, age as well as the number and type of treatment appointments received by the patient over a three month period.

These statistically significant results raise two areas for discussion in this section; firstly, the issue of the result's clinical importance and second, the potential theoretical mechanism responsible for this outcome.

6.2.1 Clinical Importance of Findings

The clinical significance of this study's results can be viewed both in relation to patient dental state anxiety, and also in relation to patient dental trait anxiety.

The Dailey et al.,[17] and Hull et al.,[18] studies, considered the effect of MDAS handover on patient dental state anxiety. In each case, a clinically significant beneficial effect was reported when patients handed their MDAS to the dentist. Both studies attribute clinical significance in STAI-S change score, in line with the work by Wardle et al., [218] where a 0.6 drop in STAI-S scale was considered to be of clinical importance.

According to Study One however, simply handing over the MDAS form to the dentist appeared to have no statistically significant effect. It should be noted however that the clinical significance of the Hull et al.,[18] result was directly related to a 'discussion' of dental anxiety taking place. Indeed, MDAS instruction was given to dentists prior to study commencement in both the Dailey et al.,[17] and Hull et al.,[18] studies.

In addition, dentists could well have been aware of the MDAS form's connection with dental anxiety discussion, due to previous undergraduate and postgraduate training. It could be argued therefore, that these dentists were actually receiving an educational intervention similar to those highlighted in the Stewart[80] review. Interestingly, according to this review it was only when the health profession received a communication education intervention, that patients' emotional status was affected.

In this study however, dentists were not only unaware of MDAS use but had no additional training from the researcher or special training events. In other words, there was no health professional educational communication intervention.

The results of Study One in relation to dental state anxiety therefore must be unpacked in relation to the observational part of the study (Study Two). Here non-adherence to study protocol (i.e. the patient not being able to handover their MDAS to the dentist) acted as a barrier to the fall in dental state anxiety experienced post treatment. Patients, who adhered to the protocol, experienced a three point drop in the mean STAI-S score. While in those who did not adhere, this three point drop was prevented. In other words, a clinically significant negative effect was produced through non-adherence.

Clinically, this means that 'blocking' of MDAS transfer affects how a patient responds immediately following their dental appointment. Indeed, in such cases, patient's dental anxiety essentially remains high, even in the final phase of their dental appointment. Following on, it is important to note that dentists tend to provide post-operative and preventive advice at the end of treatment appointments.

If patients remain as dentally anxious as they were on surgery entry, then this presents an issue in relation to their ability to retain such important information. This in turn may pose a possible medical-legal issue particularly if additional written information is not provided by the dentist.[10]

In relation to dental trait anxiety, it should be noted that neither Dailey et al.,[17] or Hull et al.,[18] measured the longer term effects of MDAS handover on dental anxiety.

Study One in this mixed methods design therefore went on to explore this issue. The results of this study however, showed no statistically significant effect when MDAS was handed over to the dentist. Study Two, then went on to highlight that, perhaps, the lack of dentist instruction in relation to MDAS use was the main contributing factor. Indeed, the observational results of the study highlighted dentists' difficulty in handling expressed VNVC, in relation to patient dental anxiety.

Indeed according to these study results, patients who received consistent 'reduce-space' responses from their dentist had their dental anxiety reduction impeded by 3.6 MDAS scale points. This clinically significant reduction in the fall of dental trait anxiety caused by the dentist 'blocking' further discussion of a patient's dental anxiety, was shown to be experienced irrespective of the number and type of appointments received thereafter.

In other words, not addressing the emotional needs of the patient effectively in the first two minutes of the dental appointment can influence a patient's longer term anxiety status. Clinically this result is important, as, theoretically, patients who remain extremely dentally anxious for longer are more likely to exhibit avoidance behaviour.

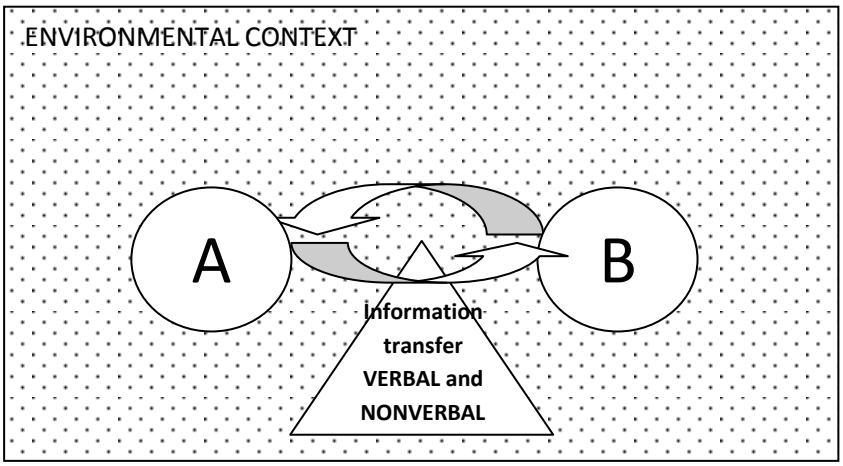
Hence the failure to attend for treatment appointments will increase their treatment need.

In addition, according to a recent cross-sectional study by Hill et al.,[119] dentists tend to feel stressed when treating uncooperative, anxious patients. If patients remain more dentally anxious for longer then, the dentist will have to undertake more of the treatment plan with a highly anxious patient. This in turn will feedback to the dentist's work related stress (see Figure 30).

6.2.2 Consideration of Possible Explanations for Study Results

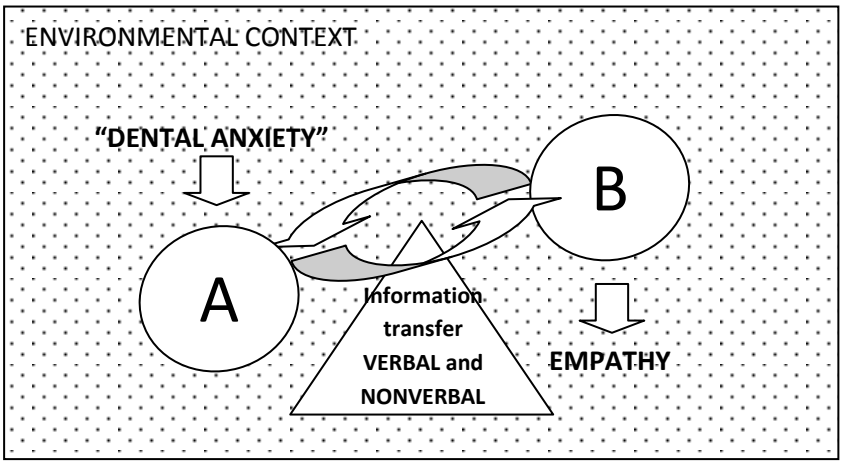
Theoretically, to explain these results, the relationship between dentist and patient, at its most basic level, should be discussed. According to Barnlund's transactional model,[66] the patient-dentist dyad can be viewed almost as a distinct entity whose fulcrum or pivot point is the unimpeded information transfer between patient and dentist (see Figure 27).

Figure 27: Barnlund's Model based on Effective Communication



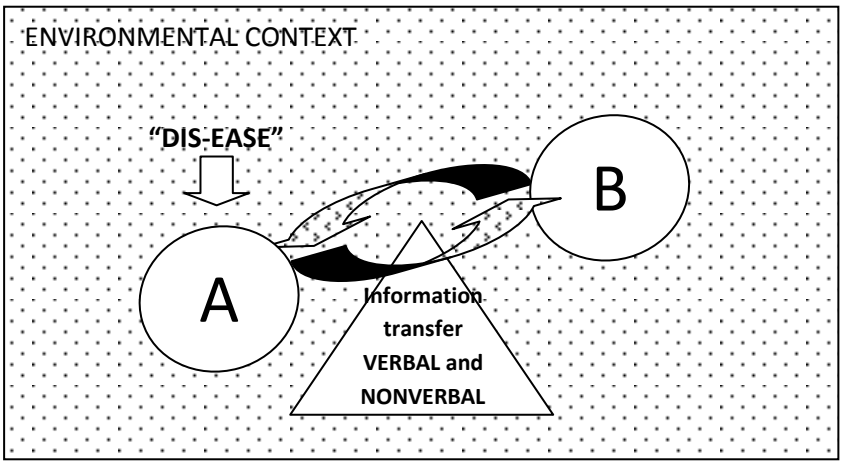
According to the composite theoretical concept of 'balance', previously developed in this thesis, 'real relationship' is based on effective communication. In such cases, individuals are able to interact by adapting their communication style to the emotional needs of the other. In the case of both the Dailey et al.,[17] and Hull et al.,[18] studies, dentists were not only able to accept the patient's dental anxiety when it was expressed, but from self-reports they were also able to deal with it by exhibiting empathic, effective emotional communication. This therefore appeared to result in patient dental state anxiety reduction (see Figure 28).

Figure 28: Effective Communication resulting in Dyadic Re-balance



In this thesis however, as no communication education in relation to patient expressed emotion had been provided, dentists were unable to deal effectively with the patient's dental anxiety. The result was a reduction in the fall of patient dental anxiety as dentists blocked the patient emotional communication; either in relation to MDAS handover or via expressed VNVC (see Figure 29).

Figure 29: Dyadic Imbalance in relation to Ineffective Communication

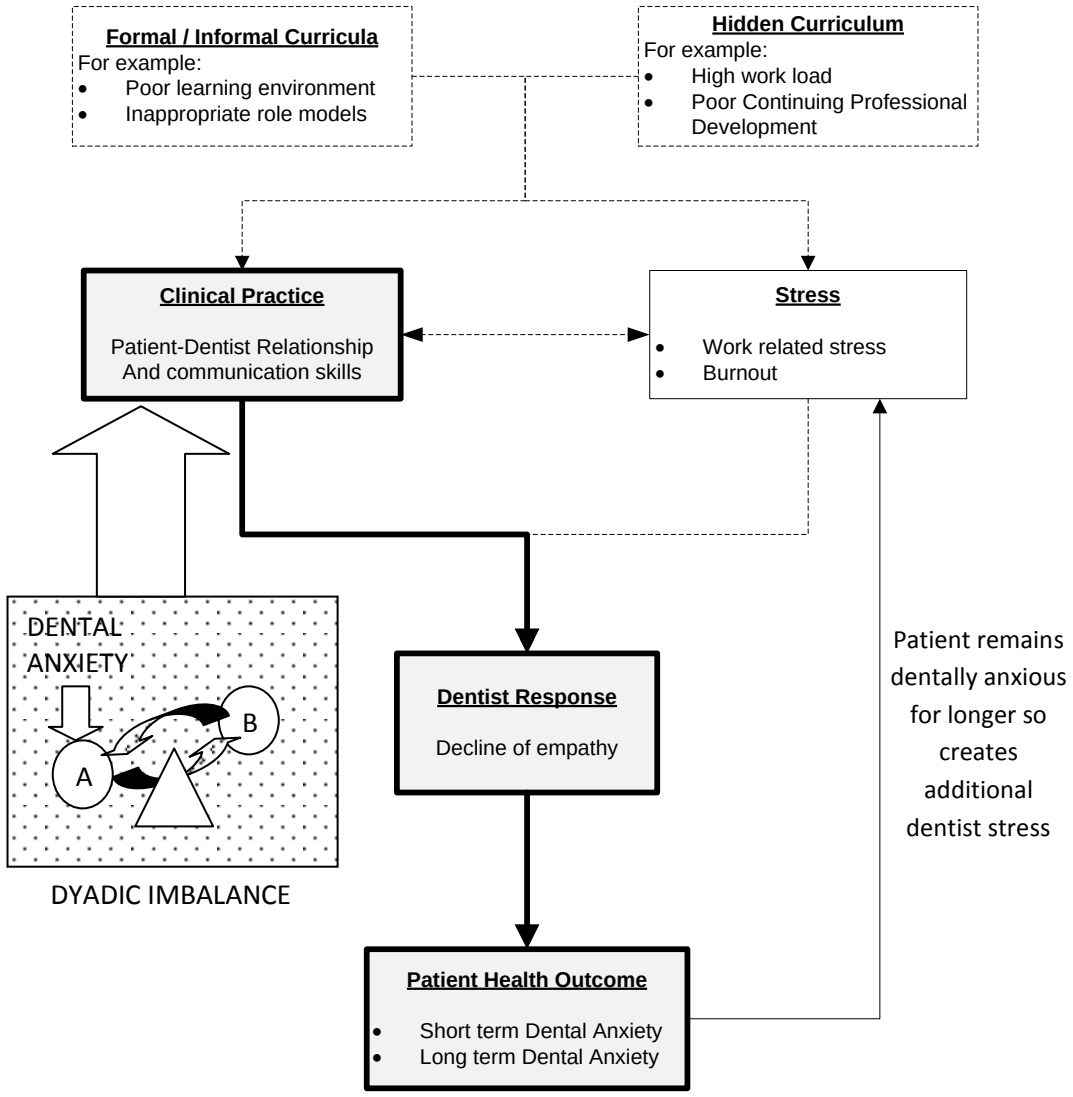


This result can again be illustrated in the model altered from Neumann's original framework (see Figure 30).[199] Here the effect of a patient's dental anxiety and dentist's ineffective communication skills result in less empathic dentist responses and in turn effects patient dental anxiety status. As the patient remains more dentally anxious for longer, the result is that the dentist will have to undertake more of the required treatments (which may be over several appointments) on an extremely anxious patient. This therefore will contribute to dentist work related stress.

6.3 Comparisons with Existing Literature

The results of this mixed methods study will now be considered in light of the current evidence base. Here, although there is a general understanding that effective communication is important, the actual consideration of communication elements as factors in improving health outcome has up until now, been largely by-passed in dentistry.

Figure 30: Neumann's Model highlighting Patient Dental Anxiety Feedback



Adapted from Neumann et al.,[199]

Previous adult dental communication studies by field leaders like Koerber et al.,[24] Sondell et al.,[25] and Kulich et al.,[26] despite providing in depth communication analyses of the patient-dentist dyad, failed to provide any health outcome measures to investigate the implications of the dyadic communication process. Indeed, not one of all these pioneering dental communication studies was set in Primary Dental Care, focusing instead on the specialist clinic.

A recent systematic review by Zhou et al.,[219] does go some way to investigate the link between certain dentist behaviour and health outcome, demonstrating that "empathic working style and appropriate level of physical contact accompanied by verbal reassurance"[219] reduced anxiety related behaviours in the dental setting. This review however, only focused on childhood dental anxiety. There remains therefore, a lack of evidence in relation to the effects of the *adult* Primary Dental Care dyad.

Indeed, even within general healthcare, there is (on first inspection of the literature) a noticeable lack of evidence investigating the effect of the Primary Care dyad on adult patient anxiety.

It was this weakness within the current evidence base that prompted the undertaking of a systematic review as part of this thesis; to investigate possible links between effective healthcare provider face to face communication and a decrease in patient anxiety and anxiety related health outcomes in Primary Care. Indeed, despite a lack of continuity and validity of anxiety measures, study results support this relationship.

In adult Primary Dental Care, initial steps to address this current evidence gap have been undertaken.

The Hull et al.,[18] randomised controlled trial, based on the original Dailey et al.[17] study, provided support for the hypothesis that patient-dentist interaction influences patient health outcome. Indeed, the study concluded that the reduction in dental state anxiety (seen in both the Dailey et al.,[17] and Hull et al.,[18] studies) associated with MDAS handover, resulted only when an effective discussion of dental anxiety had occurred. This ability for the patient to "fully express feelings and opinions" was also highlighted by Stewart's systematic review, where this was seen as an effective element of an appointment's initial History taking period.[80]

The results of this mixed methods study, although not a carbon copy of those obtained in the previous Dailey et al.,[17] and Hull et al.,[18] studies, does provide support for the fact that the quality of the patient-dentist interaction, even within the initial 'history taking period', is strategic to patient dental anxiety reduction.

The alignment of this study with the results of both the Dailey et al.,[17] and Hull et al.,[18] studies, can be further substantiated by considering them in more detail. Both studies, recruited dentists well versed in the use of MDAS either at undergraduate and /or postgraduate level. In addition, the researcher in both studies provided instruction in relation to MDAS prior to study commencement.

In other words, in both studies dentists were not only aware of how to use MDAS but also its significance in relation to discussing patient anxiety. Indeed, Dailey et al.,[17] even suggests that when presented in the intervention group, MDAS was used by dentists as a "prompt" for further discussion, highlighting a familiarity with this tool.

In contrast, recruited NHS Highland dentists were unaware of the significance of MDAS, having been given no additional training in relation to its use.

Indeed, MDAS is neither routinely taught in Scottish Dental Schools nor was a topic of recent Continuing Professional Training in the Highland area.

Study vignettes support this claim, demonstrating the dentists' confusion in relation to the handover of the MDAS form. Indeed, the null effect in dental state anxiety highlighted in the randomised cross-over study (Study One) could in fact be a result of this phenomenon, so supporting inversely both Dailey et al.,[17] and Hull et al.,'s[18] results.

Despite their interesting work, both Dailey et al.,[17] and Hull et al.,[18] were unable to demonstrate any long term dental anxiety effects as they did not conduct a follow-up assessment. In addition they were unable to identify the important components of VNVC used in the dental interaction to explain any reduction of dental anxiety.

This mixed methods study addresses both these current evidence deficits, providing the first insight into the effective elements of dental communication and their impact on dental trait anxiety levels.

Interestingly, in relation to the current healthcare evidence base, the 'blocking' effect exhibited by dentists in this study has also been highlighted previously by Maguire et al.,[220] as a barrier to effective communication between doctors and patients.

Indeed, the results of this study challenge current thinking with regard to highly anxious dental patients, by suggesting that the simple use of certain communicative components, even within the first few moments of a dental interaction, could significantly influence a patient's dental anxiety not only in the short term but also have long term effects. This result is therefore of clinical importance.

6.4 Clinical Implications of Study

Previous studies demonstrating anxiety reduction in relation to highly dentally anxious patients have tended to focus on more time consuming and invasive interventions. Pharmacological interventions (e.g. sedation) to by-pass dental state anxiety or time consuming psychological options to treat both dental state and trait anxiety have often been considered the main way of dealing with dentally anxious patients.[125,126,127,128] These options however, have often been considered to be out with the remit of the routine dental appointment.

This study therefore provides a simple alternative. By suggesting that small changes in the way the dentist communicates with a patient (i.e. by avoiding the continual use of 'reduce-space' responses) and by allowing patients to hand over forms containing emotional information they regard as important, will cause a patient's long term and short term dental anxiety to reduce.

The reported effect on long term dental anxiety has major potential implications in clinical dentistry. Patients instead of being seen as simply dentally anxious or dentally 'phobic' can instead be viewed along a continuum[127] where through effective communication and the production of a balanced patient-dentist dyad, dental anxiety may be defused, resulting in a less anxious patient. This in turn has positive implications for the profession who have often been shown to dislike treating patients with extreme dental anxiety.[119]

It should be noted that the results of all three studies (Dailey et al.,[17] Hull et al.,[18] and this mixed methods study) involve the completion of MDAS by all patients.

Although the handover of MDAS in this study was not shown to have a significant effect on patient dental anxiety, as discussed previously in this Chapter, the lack of dentist training relating to MDAS use may well have been instrumental.

There is therefore a training need within the profession in relation to MDAS use, particularly since it had been highlighted in current Scottish dental guidance development, as an important part of a comprehensive dental assessment.[15]

It should, however, be noted that this lack of knowledge in relation to MDAS, may not be the only reason for the reported dentist 'blocking' effects in this study. Willingness to enter into such discussions with patients may also be a reason for dyadic imbalance. In such cases the problem occurs when patients are not able to contain their dental anxiety, using cues and concerns to elicit additional support from their dentist. Here dentists may feel that they are opening a "can of worms" being ill equipped or unable to provide the kind of support that the patient may need.[119]

Indeed, this unwillingness to engage the patient at an emotional level may find its root within the stresses and strains of being a dentist in a busy every-day dental clinic. Here the dentist's own anxieties as highlighted in the adapted Neumann et al., model[199] (see Figure 30) may prevent dyadic balance in the clinical interaction.

Despite the possible challenges, this study clearly indicates that the ability to establish good quality patient-dentist relationships has short and long term advantages to both patient and dentist alike.

According to Beach et al.,[76] the 'relationship' is the next step in the evolution of healthcare. The concept of relationship-centred care and its proven healthcare benefits moves away from the concept of patient centred-care where the practitioner has the option to step-back from the interaction by acting out a professional front. In contrast, relationship-centred care is based on 'truthful' interaction. Here information is allowed to flow through appropriate unimpeded communicative interchanges. The result is to cement a real patient-health provider relationship and effect patient health outcome.

6.5 Limitations and Strengths of the Study

This section, aims to consider the limitations and strengths related to the use of this mixed methods study within its Primary Dental Care context. This study uses a combination of two elements, a randomised cross-over trial (Study One) and an Observational study (Study Two) as a means of addressing the project aim.

It could be argued that the quality of such mixed method approaches is only as strong as its constituent parts. The limitations of each element of this mixed methods study and their combined implications, will now therefore be considered.

In relation to the randomised cross-over element of this study (Study One), limitations stemmed mainly from the challenges incurred by running such a study within clinical parameters.

This study faced challenges in relation to ensuring adequate study power. According to study protocol, patients could only complete the MDAS form on the day of their dental treatment appointment. This meant that full compliance with the inclusion criteria was not known until that patient attended. Indeed, although many patients were happy to take part in the project, they were often not of a high enough dental anxiety level to be accepted into the study.

This problem was further compounded by the choice of study design and its relationship with dentist retention. In the case where a dental practice dropped out of the study and no other practice dentists were willing to take part, all related data became obsolete. This meant having to start recruitment again at an alternative location.

In relation to patient recruitment, it could be suggested that only those patients who were interested in the effects of communication on their dental anxiety were actually involved in this study. Yet the issue of selection bias could indeed be argued as a limitation of any clinical research where patients have the option to choose whether or not they wish to participate.

In all, of the 54 patients consented to take part in this study, only 47 completed the three month follow-up, one less than required to power the cross-over element.

In relation however to the major challenges encountered in this study in both patient recruitment and dentist retention, attrition could be considered as minimal, having resulting in no systematic differences between experimental and control groups.

In relation to the overall mixed methods study design, the apparent problems encountered by the cross-over element in patient and dentist recruitment, could indeed be attributed to the presence of the observational arm of the study. It could be argued that without the video recording element, the acceptance of the experimental part of the study could well have been higher. This can be seen in the high recruitment numbers achieved by both Dailey et al.,[17] and Hull et al.[18]

Despite these challenges, every effort however was made in the experimental study to ensure a quality randomised cross-over element. This involved sequence generation and dentist allocation being undertaken by an independent statistician (KC, DHSRU) prior to study commencement, as well as the incorporation of appropriate study blinding strategies.

The randomised allocation and actual study design was successfully concealed from both dentists and patients, although dentists were aware of the communication element of the project. Efforts, at study commencement to blind the dentists to its focus on dentally anxious patients, were largely unsuccessful. This was mainly due to the display and distribution of study patient information in line with Ethical guidance.

It could be argued however that this minimal initial blinding could have been enough to ensure that those dentists with a special interest in dental anxiety did not volunteer for the study, hence preventing recruitment bias.

Despite these strategies, certain elements could not be concealed. Both patient and dentist could not be blinded to the use of the video camera due to ethical and technical factors. This could be considered a limitation of the observational study.

Nevertheless, MDAS handover was successfully concealed. Dentists did not receive any instruction or information relating to the use of MDAS and were unaware of its role in the study design.

It should however be noted that quantitative data on its own, only allows for the consideration of study outcomes. In other words, as highlighted by Borkan "you 'see' only what you are looking at".[221] In relation to the mixed methods study approach, you are able to "expand the gaze to key elements that were never elucidated or even previously considered".[221]

The strength of this mixed method study therefore lies in the two independent yet tandem perspectives provided. Without the observational element, the results of the randomised cross-over study would simply have shown no significant intervention effect. This in turn could establish an opposing evidence base relating to the ineffectual use of MDAS in the dental clinical environment. Instead, by using a mixed methods approach, clarity is provided to interpret the randomised cross-over study results within their clinical context which in turn improves their generalisability.

6.6 Recommendations

The resulting recommendations of this investigation lie within the parameters of dentist education and patient empowerment. To assume the auspices of the balanced patient-dentist dyad, there is a need to establish a 'true' relationship between both parties involved in the interaction.

To do this, dentists must be educated and sensitised to the communicative elements expressed by patients who require greater assistance in dealing with their dental anxiety. In turn, such patients should be allowed the opportunity to express their needs for support within the everyday dental setting. The use of a simple patient anxiety self-assessment form (e.g. MDAS) not only provides patients with a medium to do this but also provides dentists with a tool to prompt further informed clinical discussion.

6.7 Dissemination and Implementation of Results

According to Clarkson et al.,[222] dissemination and implementation can be described as a spectrum activity where the act of dissemination relates to "raising awareness" relating to a piece of research and its outcomes, while implementation involves the process of getting that evidence incorporated into everyday clinical practice. This process however also known as Knowledge Translation (KT)[223], has been shown to be complex in nature and haphazard in effectiveness.[224] Indeed, with its roots within the field of Health Communication, its diverse and unpredictable nature can only be expected.

6.7.1 Dissemination of Results

In relation to study outcomes, a two way dissemination of results has been proposed: first for patients and second for the health profession.

- **Patient Local Level Dissemination**

  At local level, NHS Highland salaried dental patients were made aware of this study early in the recruitment phase. Distribution of patient leaflets and the display of a project poster in the waiting rooms of participating practices, aimed to raise patient interest. Patient leaflets, also provided additional dissemination by supplying a web-address for those wishing further information regarding study outcomes. All patient information was vetted by the North of Scotland Research Ethics Service to ensure patient accessibility.

- **Patient National Level Dissemination**

  At a national level the Chief Scientist Office (CSO), the funding body of this research study, was instrumental in early stage project awareness. As a means of highlighting current research to patient groups, this project was presented before the CSO Public Involvement Group in March 2010. In addition, at the end of the research project a "Focus on Research" patient summary was written and approved by CSO and is now available on their general website.[225]

- **Dentist Local Level Dissemination**

  In terms of dissemination within the dental profession, study awareness began at a local level in NHS Highland's SDS. This was achieved as part of dentist recruitment through presentations undertaken within each CHP's Clinical Dental Discussion Group. Dentists and dental teams who later participated in the project went on to receive a summary of project results as part of their debriefing pack.

- **Health Care National Level Dissemination**

  Wider dissemination across specialties was also provided through the CSO Clinical Academic Fellowship programme where this project was chosen for presentation at the annual CSO fellowship meeting. This was supplemented by the submission of a report highlighting study results for peer review via the CSO Review Committee. Further dissemination through scientific and professional channels is intended via peer reviewed publication of both this study's systematic review and primary research results.

Ultimately it is hoped that this information will add to the Health Communication evidence base within the field of dentistry to establish a basis for knowledge transfer into everyday clinical practice.

6.7.2 Implementation of Results

Based on the recommendations highlighted in Section 6.6, the author suggests the following pathways for translation of study results (on development of the evidence base) to ultimately impact dental practice.

- **Undergraduate Level**

  In relation to bench marking standards for undergraduate dentistry,[226] students should not only be able to assess patient anxiety levels using psychological inventories but also be able to use that information in relation to managing "fear and anxiety with behavioural techniques".[226]

This study, along with the work of both Dailey et al.,[17] and Hull et al.,[18] highlights the importance of not only using an inventory like MDAS but also in its informed use by the dentist. As undergraduate benchmarking also highlights the importance of knowledge and understanding in relation to "communication between dentist and patients",[225] then this study's results paves the way for a new aspect of behavioural science teaching, considering the affect of communicative elements on patient health outcome.

- **Postgraduate Level**

According to the General Dental Council (GDC), dental practitioner revalidation will be introduced in 2014.[227] The proposal, currently in the consultation phase since October 2010, would herald the biggest change to dentistry since Continuing Professional Development (CPD) became mandatory for all UK dentists in 2002.[228]

Using an evidence framework, this five year revalidation cycle will require the dentist to meet standards under four main domains: clinical, management and leadership, professionalism and communication.

The results of this study, along with the growing evidence base in the area of the patient-dentist dyad, may be an important element within the communication domain of this structure, not only within the context of dental anxiety reduction but also in relation to informed consent and litigation.

Indeed, Dental Protection UK is already hosting CPD courses under the title 'Communication Skills Workshops' based on the fact that "70% of litigation is related to poor communication".[229]

This, coupled with recent concerns relating the dentally anxious patient to a future source of potential litigation,[10] means that study results could easily be incorporated into postgraduate education. This could and should be easily mirrored by MDAS training both in use and application.

- **Audit and Clinical Governance**

Clinical Audit is considered a key element of Dental Governance.[230] It has been considered a way in which guidelines can be translated into clinical practice by providing a 'gold standard' by which the audit process allows current practice comparison. By developing the evidence base related to 'patient-dentist dyadic effects', the results of this study may help to contribute tailored dental communicative guidance. This guidance in turn, may be used in clinical audit.

- **Government Policy**

In relation to Government policy, effective communication is often seen as a key element e.g. Options for Change, [231] yet its actual composition is often poorly defined. This study therefore paves the way for a definition of quality communication elements in the patient-dentist interaction.

6.8 Further Research

With regard to recommendations for further research, the results of this mixed methods study advocate a twofold approach. First, in relation to the concept of the mixed methods study design in dentistry and second, in relation to the effects of the patient-dentist dyad in terms of health outcome.

Currently within the dental profession, the randomised controlled trial is viewed as the ultimate primary research approach in establishing quality evidence.[232, 233]

Within Health Services Research there has been a recent increase in the interest in the use of mixed methods studies particularly in relation to its ability to "engage with the variety of questions relevant to the complexity of health care".[234] In other words, a purely quantitative approach often provides only a two dimensional view of clinical outcomes; one which is clearly highlighted in the results of this project.

Incorporating mixed methods studies in dentistry may provide a new way to truly understand clinical outcomes, particularly in relation to the so-called 'placebo effect' of the patient-healthcare provider dyad. In addition, although this study provides the first step towards understanding the true patient-dentist dyad, further investigation is still required.

Studying the effect of dyadic balance, using the same study protocol but with fully informed dentists proficient at MDAS use and interpretation, would allow further investigation of study results. In addition, communication and its effects in relation to other patient groups should also be developed e.g. children, those with learning difficulties etc, to further establish and develop the evidence base

Chapter 7

Conclusion

7.0 Conclusion

The conclusion of this investigation can be stated as follows:

Verbal and non-verbal communication is fundamental to establishing dyadic balance within the first two minutes of the patient-dentist interaction. Blocking communication, either behaviourally or from an affective (emotional) viewpoint, results in a clinically significant lack of decline in patient dental anxiety reduction, irrespective of age, gender and number of subsequent appointments over a three month period.

This is the first study to identify effective communication elements in the patient-dentist dyad using the health outcome of dental anxiety status. It therefore paves the way for future research within the fields of Health Communication and Special Care Dentistry. In addition, it promotes the establishment of dentally derived and tailored communication teaching at undergraduate and postgraduate levels.

This body of work indicates that the dentist's ability to communicate effectively within the first few minutes of a clinical interaction is as important, if not more important, than what (s)he does technically.

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Appendix 1

Communication Theory

APPENDIX 1: Theories of Communication

	Rhetorical	Semiotic	Phenomenological	Cybernetic	Sociopsychological	Sociocultural	Critical
Communication theorised as	The practical art of discourse	Inter-subjective mediation by signs	Experience of otherness, dialogue	Information processing	Expression, interaction and influence	(re)production of social order	Discursive reflection
Problems of communication theorised as	Social exigency requiring collective deliberation and judgement	Misunderstanding or gap between subjective viewpoints	Absence or failure to sustain authentic human relationship	Noise: overload; under load; a malfunction or "bug" in a system	Situation requiring manipulation of causes of behaviour to achieve specified outcomes	Conflict: alienation, misalignment; failure of coordination.	Hegemonic ideology; systematically distorted speech situation
Metadiscursive vocabulary such as	Art, method, communicator, audience, strategy, commonplace, logic, emotion.	Sign, symbol, icon, index, meaning, referent, code, language, medium, (mis)understanding	Experience, self and other, dialogue, genuineness, supportiveness, openness	Source, receiver, signal, information, noise, feedback, redundancy, network, function	Behaviour, variable, effect, personality, emotion, perception, cognition, attitude, interaction	Society, structure, practice, ritual, rule, socialization, culture, identity, co-construction	Ideology, dialect, oppression, consciousness-raising, resistance, emancipation
Plausible when appeals to metadiscursive commonplaces such as	Power of words; value of informed judgement; improvability of practice	Understanding requires common language; omnipresent danger of miscommunication	All need human contact; should treat others as persons, respect differences, seek common ground	Identity of mind and brain; value of information and logic; complex systems can be unpredictable	Communication reflects personality; beliefs and feelings bias judgements; people in groups affect one another	The individual is a product of society; every society has a distinct culture; social actions have unintended effects	Self perpetuation of power and wealth; values of freedom, equality and reason; discussion produces awareness, insight
Interesting when challenges metadiscursive commonplaces such as	Mere words are not actions; appearance is not reality; style is not substance; opinion is not truth	Words have correct meanings and stand for thought; codes and media are neutral channels	Communication is skill; the word is not the thing; facts are objective and values subjective	Humans and machines differ; emotion is not logical; linear order at cause and effect	Humans are rational beings; we know our own minds; we know what we see	Individual agency and responsibility; absolute identity of self; naturalness of social order	Naturalness and rationality of traditional social order; objectivity of science and technology

Appendix 2

References for the 88 Review Papers:

Phase One of Systematic Review

The 88 Review Papers Sourced in Phase One of the Systematic Review

YEAR	AUTHORS	TITLE	REFERENCE
2009	Street RL Jr, Makoul G, Arora NK, Epstein RM.	How does communication heal? Pathways linking clinician-patient communication to health outcomes.	Patient Educ Couns. 2009 Mar;74(3):295-301. Epub 2009 Jan 15.
2007	Rao JK, Anderson LA, Inui TS, Frankel RM.	Communication interventions make a difference in conversations between physicians and patients: a systematic review of the evidence.	Med Care. 2007 Apr;45(4):340-9.
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2005	Carlson LE, Feldman-Stewart D, Tishelman C, Brundage MD; SCRN Communication Team	Patient-professional communication research in cancer: an integrative review of research methods in the context of a conceptual framework.	Psycho oncology. 2005 Oct;14(10):812-28; discussion 829-30
2003	Michie S, Miles J, Weinman J.	Patient-centeredness in chronic illness: what is it and does it matter?	Patient Educ Couns. 2003 Nov;51(3):197-206.
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Appendix 3

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Phase Two of Systematic Review

The 25 Primary Research Papers Sourced in Phase Two of the Systematic Review

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Appendix 4

Proforma Templates One, Two and Three:

Phase Three of Systematic Review

Systematic Review Questions

Proforma One: Article Exclusion Questions

Title of Project	"Does effective face to face communication with healthcare providers decrease patient anxiety and anxiety related health outcomes in adult Primary Care patients?"

Paper Number	
First Author	
Title	
Year Published	

Any red boxes means paper is discounted

	Yes	No
1. Language other than English?		
2. Article other than original data?		
3. Study design other than a Randomised Controlled Trial?		
4. Study setting other than Primary Care?		
5. Patients younger than 16 years old?		
6. Patients have psychological problems?		
7. Communication only between Health Care Providers?		
8. Indirect Communication only?		
9. Communication involves psychologists, psychoanalysts or therapist/counsellor?		
10. No anxiety measure?		
Paper Excluded?		

Systematic Review Inclusion

Proforma Two: Article Inclusion Form

Title of Project	"Does effective face to face communication with healthcare providers decrease patient anxiety and anxiety related health outcomes in adult Primary Care patients?"

Paper Number	
First Author	
Title	
Year Published	

Participants	
Total Number	
Study Setting	
Anxiety related measure	
Age	
Sex	
Country	

Methods	
Study Design	
Total Study Duration	

Cochrane Collaboration's Tool for Assessing Risk of Bias				
Domain	**Description**	**Review Authors Judgement**		
		Summary Question		**Reasoning for Judgement**
Sequence Generation		Was the allocation sequence adequately generated?	YES/NO/ UNCLEAR	
Allocation Concealment		Was allocation adequately concealed?	YES/NO/ UNCLEAR	
Blinding of Participants, personnel and Outcome Assessors		Was knowledge of the allocated interventions adequately prevented during the study?	YES/NO/ UNCLEAR	
Incomplete Outcome Data		Were incomplete outcome data adequately addressed?	YES/NO/ UNCLEAR	
Selective Outcome Reporting		Are reports of the study free of suggestion of selective outcome reporting?	YES/NO/ UNCLEAR	
Other Sources of Bias		Was the study apparently free of other problems that could put it at risk of bias?	YES/NO/ UNCLEAR	

Interventions	
Total Number of Intervention groups	
Specific Intervention (Intervention interested in)	
Intervention details (i) Provided by? (ii) Number of times?	

Comparisons	
Number of comparisons	
Comparison details	

Outcomes	
Outcomes and time points (i) Collected (ii) Reported	
Outcome definition	
Unit of measurement	
For scales: Upper and Lower limits and whether high or low score is good	

Results	
Number of participants allocated to each intervention group	
Sample size	
Missing participants	
Summary of each intervention group	

Miscellaneous	
Funding source	
Key conclusions of the study authors	
Miscellaneous comments from the study authors	
References to other relevant studies	
Correspondence required	
Miscellaneous comments from review authors	

Proforma Two is based on the Cochrane Checklist for Data Collection

Systematic Review Exclusion

Proforma Three: Article Exclusion Form

Title of Project	"Does effective face to face communication with healthcare providers decrease patient anxiety and anxiety related health outcomes in adult Primary Care patients?"

Paper Number	
First Author	
Title	
Year Published	

Country study conducted	
Objectives	
What was done?	
Why Excluded?	

Appendix 5

Proforma Three Results

Phase Three of Systematic Review

Proforma Three Results

SECTION ONE: Characteristics of Excluded Studies from Original 25 Sourced Papers

Study	Reason for Exclusion
Helmes, 2006	This paper was taken to the Intergroup Forum for discussion.
Paper 2	This study was excluded on the basis of the genetic counselling being done by a trained therapist/councillor. It is the view of the reviewers that such an intervention from an experienced communication professional would be systematically different from one undertaken by a routine Primary Care Provider.
Izzo, 2005	This paper was taken to the Intergroup Forum for discussion.
Paper 3	
Little, 2004	This paper was taken to the Intergroup Forum for discussion.
Paper 4	
Ridsale, 1999	This paper was taken to the Intergroup Forum for discussion.
Paper 6	Although the HAD (Hospital Anxiety and Depression) scale is composed of 14 questions, 7 of which look at anxiety and 7 depression, the paper fails to separate these dimensions quoting only scoring for depression. It is the assumption of the reviewers that the depression element was the only area considered therefore for this reason the study was excluded.
Mcleod, 1997	Review groups independently agreed to exclude this paper.
Paper 7	This study was excluded as the intervention ran parallel to routine Primary Care with patients attending a six week course run by individuals trained in behavioural science skills.
Palsson, 1995	Review groups independently agreed to exclude this paper.
Paper 8	This study was excluded by the reviewer due to three main areas: 1. Study Design: The study uses a "non-randomised sample" and also appears to use of a qualitative study design, with patients describing "their experiences of the disease and nursing care in a semi-structured interview 6 months after the primary treatment. Data were coded by open coding; themes and categories were formulated."

	2. Study Setting: The study is not exclusively set in Primary care as "The intervention was put into practice from April 1991, in a surgical ward of a general hospital and in a primary health care area in the South-East of Sweden." Participants: There is also a lack of information relating to the psychological condition of subjects.
Serwint, 1991 *Paper 10*	This paper was taken to the Intergroup Forum for discussion. Despite adhering to the inclusion criteria, this study was excluded from the Systematic Review due to problems in the study design. The intervention was extremely complicated, with a number of health care providers (from both primary and secondary care) potentially interacting with each mother either on a face to face basis or indirectly. There was also a time delay between the control and intervention groups in terms of the face to face intervention. For these reasons the reviewer excluded the study.
Girgis, 2009 *Paper 11*	This paper was taken to the Intergroup Forum for discussion. This paper was excluded for a number of reasons: 1. Firstly as it is not exclusively set in Primary Care with the involvement of Oncologists in the O/GP intervention group. 2. Secondly as the TCW intervention group involved nurses based in the Cancer Council NSW helpline service who would have substantial experience in communicating effectively with patients. '"TCWs were oncology nurses with telephone counselling training who were based with the Cancer Council NSW helpline service" Finally as the TCW group would be communicating with patients indirectly by using a telephone.
Kravitz, 2009 *Paper 13*	Review groups independently agreed to exclude this paper. This study was excluded as it was not exclusively set in Primary Care. "Cancer care physicians were recruited from three health systems (UC Davis Cancer Centre; Kaiser-Permanente Sacramento/Roseville; and the VA Northern California Health System) and one private practice, all in Northern California.

	Medical, radiation, and (after March 2008) gynaecological oncologists (including both staff physicians and clinical fellows) were deemed eligible if they saw patients at one of the participating sites and were in clinical practice at least 20% time (i.e., at least 1 full day per week)."
Copello, 2008 *Paper 14*	Paper originally included but excluded during Proforma Two completion.
Brown, 2008 *Paper 15*	Review groups independently agreed to exclude this paper. This paper was excluded by the reviewer primarily due to the absence of anxiety scoring. Mothers were asked if anxiety was discussed at their consultation but not whether or not they felt anxious. "During today's visit did your doctor/nurse practitioner discuss any stresses or strains you are feeling yourself?" Mothers also reported distress using the General Health Questionnaire. It is a pure state measure, responding to how much a subject feels that their present state "over the past few weeks" is unlike their usual state. The General Health Questionnaire (GHQ) is a self-administered screening test, designed to identify short-term changes in mental health (depression, anxiety, social dysfunction and somatic symptoms).
Heritage, 2007 *Paper 16*	This paper was taken to the Intergroup Forum for discussion. This paper was excluded by the reviewer due to study design. The study is not a randomised controlled trial but a "nested, cross-sectional study"
Gall, 2007 *Paper 17*	Review groups independently agreed to exclude this paper. paper was excluded by the reviewer due to the study setting. The study was based in both Secondary and Primary Care not Primary Care exclusively. This is highlighted by the involvement of secondary care provider i.e. surgeons "patients were randomized (Excel random number generator) to GP or surgeon follow-up and were reviewed in GP rooms or surgeon outpatient/private rooms."
Lovander, 2005 *Paper 18*	Review groups independently agreed to exclude this paper.

	A form of indirect communication was used in this study as some of the participants relied on an interpreter. This study was therefore excluded from the systematic Review. "Professional interpreters were available at the patient's request."
Wattchow, 2006 *Paper 19*	Review groups independently agreed to exclude this paper. The reviewer excluded this study on grounds that it was not exclusively set in Primary Care. "The setting and environment of follow-up (Primary vs Secondary care) constituted our intervention."
Stuckey, 2009 *Paper 20*	Paper originally included but excluded during Proforma Two completion. This study was excluded by the reviewer as patient anxiety was not clearly measured although emotional distress (PAID) was.
Haskard, 2008 *Paper 21*	This paper was taken to the Intergroup Forum for discussion. The reviewer excluded this study due to the lack of a patient anxiety measure. The study however does consider physician stress. "all physicians completed the physician's stress and life satisfaction questionnaire"
Lauritzen, 2008 *Paper 22*	Paper originally included but excluded during Proforma Two completion. The reviewer excluded this study as there was no mention of anxiety scoring. There was however use of the GHQ-12 questionnaire. This was interpreted as "psychological reaction".
Farmer, 2007 *Paper 23*	This paper was taken to the Intergroup Forum for discussion. Commentary
Kulzer, 2007 *Paper 24*	This paper was taken to the Intergroup Forum for discussion.
Bakker, 2007 *Paper 25*	Review groups independently agreed to exclude this paper. The reviewer excluded this study on the grounds that the patient group were suffering psychological problems "we use the term stress-related mental disorder (SMD) to indicate relevant dimensions of psychopathology that are sub-acute, but not yet chronic, and clearly related to stress."

SECTION TWO: Characteristics of Excluded Studies from Snowballing (SB).

Study	Reason for Exclusion
Peck, 2004 *SB Paper 1*	Review groups independently agreed to exclude this paper. ***"DESIGN:* Prospective cohort study."** Also but principally does not look at the effect of communication on anxiety but patients expectations.
Jung, 1997 *SB Paper 2*	Review groups independently agreed to exclude this paper. Reasons for exclusion: 1. This is not a Randomised Controlled Trial but a cross-sectional study. 2. Does not look at the effect of direct communication on anxiety. Only questionnaires are used No anxiety measure.
Moral, 2001 *SB Paper 4*	Review groups independently agreed to exclude this paper. Reason for exclusion: There was no anxiety measure in this study.
Johnson, 1988 *SB Paper 5*	Review groups independently agreed to exclude this paper. The reasons for study exclusion are as follows: 1. As these patients are attending for cancer treatment and the study is run form "the treatment facility" then it is assumed that this is within secondary care and not primary care. 2. It is only the effect of the taped messaged that are looked at not their effect on a resulting consultation, therefore this is indirect communication and should be excluded from the review.
Thomas, 1987 *SB Paper 6*	Review groups independently agreed to exclude this paper. No anxiety measure recorded
O'Connor, 2003 *SB Paper 7*	Review groups independently agreed to exclude this paper. This is not Primary Research but an Education/Debate article

Gabbay, 2006 *SB Paper 8*	Review groups independently agreed to exclude this paper. This study was excluded despite an all No answer to the exclusion questions in Proforma One because the intervention was the use of the Nurse case manager. As the control and intervention groups were being seen by different individuals this would not allow for a fair comparison of communication effectiveness.
Kaplan, 1989 *SB Paper 9*	Review groups independently agreed to exclude this paper. This is not Primary Research but Secondary Research as this is a review.
Putnam, 1988 *SB Paper 10*	Paper originally included but excluded during Proforma Two completion. No anxiety measure

Appendix 6

Chief Scientist Office

Clinical Academic Training Fellowship Award Letter

Chief Medical Officer Directorate
Chief Scientist Office Division

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The Scottish Government

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Research and Innovation Services
University of Dundee
Nethergate
Dundee
DD1 4HN

Our ref: CAF/07/02
4 December 2007

Dear Mr Findlay

CLINICAL ACADEMIC TRAINING FELLOWSHIP
Understanding effective communication in dental primary care: the dentally anxious patient, an example of special care dentistry

On behalf of Scottish Ministers, I am pleased to offer The University of Dundee a Clinical Academic Training Fellowship on behalf of Ms Jenny Hally, as specified at Annex A. The Fellowship is offered subject to the Conditions of Grant set out in Annex B to this letter which are incorporated herein brevitatis causa and is subject to the Scottish Parliament making the necessary funds available to the Scottish Government Health Directorate.

Please read the following information carefully and use the above reference number in all future correspondence with the office.

Conditions of Award

It is important that you continue to consult the Conditions of Award for the duration of the Fellowship. Any potential changes in the substance of the project **must** be discussed with the appropriate contact within CSO.

Start Date
The Fellowship must begin within 6 months of the date of acceptance of the award and if there is a risk that it will not, you must contact the appropriate contact within CSO to agree a suitable start date. We reserve the right to review our offer of support if the start is unduly delayed.

Ethical Approval
If ethical approval is required for the project element of the Fellowship, a copy of the approval must be sent to CSO. Management approval must also be obtained from the relevant NHS R&D Office(s).

Reports and Monitoring
Progress and Final Reports on projects must be provided on the due dates. All Fellowships require Progress Reports at 6, 18 and 30 months.

A final report (**Form 4**) should be submitted within one month of the end date of the Fellowship along with a statement of expenditure on **Form 8** detailing expenditure in the same categories as in the specification. We will not make the final payment until you have submitted these documents, and the report has been deemed satisfactory.

A one-day meeting for all Fellows will be held each year and the Fellow will be expected to make reasonable efforts to attend.

Publications and Communications arising from the Fellowship
All publications and communications arising from the research carried out under the Fellowship are subject to our Conditions of Grant and must acknowledge the support of CSO. In addition a copy of the final, peer-reviewed version of all papers arising from the funded research and accepted for publication must be deposited in a publicly accessible repository (UK PubMed Central when this is established) and be made freely available within 6 months. Papers must cite the CSO grant reference number.

Publicity
We may wish to publicise your project and will place a copy of the Project Summary on our website upon completion.

Travel to Conferences
Requests for funds to attend conferences will be considered separately. The form (**Form 6**) can be downloaded from the CSO website. CSO would normally expect to fund attendance at a maximum of one conference per year, but funding is not guaranteed.

Action Required

As grantholder you are asked to take the following action and to liaise with the Sponsor(s) and Applicants for this award as appropriate.

- Sign and date this award letter, retain a copy and return the original to CSO along with the Acceptance of Conditions of Grant form (**Form 5,** enclosed) signed by the Grantholder, Applicants and Sponsor(s) of the award within 28 days of the date of this letter.
- A Start Certificate (**Form 7,** enclosed) must be completed by your Finance Office and returned to CSO before the Fellowship commences. For administrative purposes, the start date will be the first day of the month in which expenses are incurred.

No payments will be released from CSO until the above documentation is received.

This letter has been copied to Ms Jenny Hally for information.

Yours sincerely

KAREN FORD
CSO ADMINISTRATION

cc Ms Jenny Hally

Encs

Acceptance of Conditions of Award

On behalf of The University of Dundee, I accept the offer of award specified in this letter of award from Scottish Ministers acting through the Chief Scientist Office dated 4 december 2007 and the terms and conditions contained herein.

Signature:
Full Name:
Position:
Date:

Appendix 7

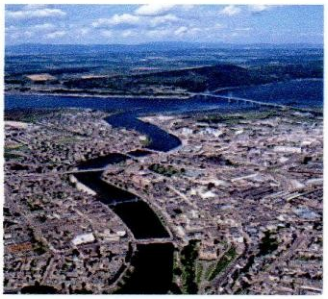
Presentation for Dentist Recruitment

“Effective Communication in Primary Dental Care”

Effective Communication in Primary Dental Care

Jenny Hally
CSO Clinical Fellow

Background



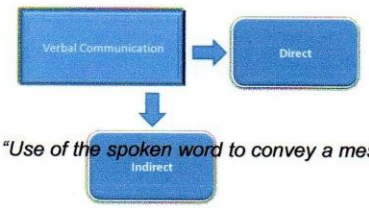
Background

NHS QIS Safer practice Notice 10
(January 2008)

- 'Being open is about communicating effectively with patients particularly in the process of treatment....
  In doing so NHS boards can potentially reduce complaints.'
- 'NHS Highland has stated that procedures should involve patients to ensure that they are kept informed, reduce concerns and potential for complaints.'

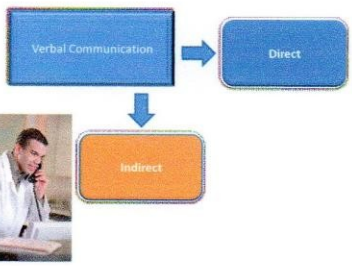
Communication

Communication

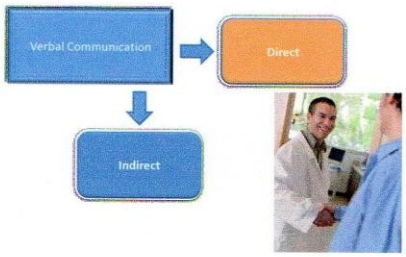


"Use of the spoken word to convey a message"

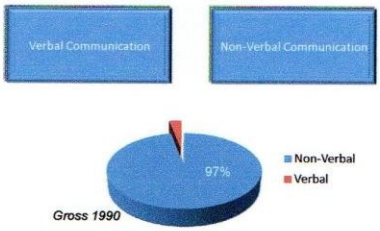
Communication



Communication



Communication



Communication

Non-Verbal Communication

"Use of wordless messages to convey information"

Communication

Communication

"Communicate emotions and attitudes"

Communication

"Communicate emotions and attitudes"

Communication

Verbal Communication

Non-Verbal Communication

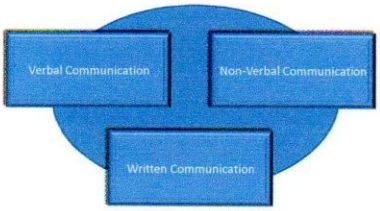
Written Communication

Communication

"The use of l *a message"*

Written Communication

Communication



The Project

"Effective Communication in Dental Primary Care"

The Project

"Effective Communication in Dental Primary Care"

How do the 3 elements of communication effect the patient/dentist interaction?

The Project

"Effective Communication in Dental Primary Care"

NHS QIS Safer practice Notice 10
(January 2008)

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The Project

"Effective Communication in Dental Primary Care"

- 6 Salaried NHS Highland Dentists
- 184 patients (~30 patients per dentist)

The Project

"Effective Communication in Dental Primary Care"

- 6 Salaried NHS Highland Dentists
- 184 patients (~30 patients per dentist)
- Treatment sessions will be recorded

Observer Software

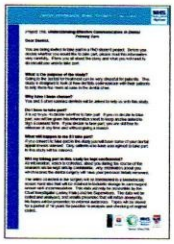
"Coded using the Roter Interaction Analysis System"

What is involved

- A practice visit

What is involved

- A practice visit
- Information Leaflet

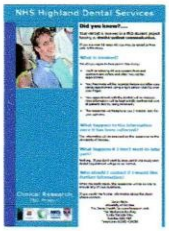


What is involved

- A practice visit
- Information Leaflet
- Placement of video camera

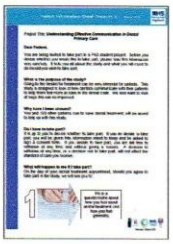
What is involved

- A practice visit
- Information Leaflet
- Placement of video camera
- Display patient poster



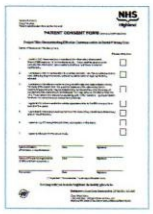
What is involved

- A practice visit
- Information Leaflet
- Placement of video camera
- Display patient poster
- Initial patient invitation



What is involved

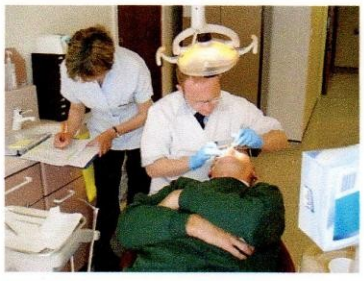
- A practice visit
- Information Leaflet
- Placement of video camera
- Display patient poster
- Initial patient invitation
- Recruitment of patient



What is involved

- A practice visit
- Information Leaflet
- Placement of video camera
- Display patient poster
- Initial patient invitation
- Recruitment of patient
- Pt has heart rate recorded and completes questionnaire before and after treatment

Summary



Appendix 8

Patient Consent Form

Centre Number::
Study Number:
Patient Identification Number for this trial:

NHS Highland

PATIENT CONSENT FORM (Version 5) March 2008

Project Title: Understanding Effective Communication in Dental Primary Care

Name of Researcher: Ms Jenny Hally

Please initial box

1	I confirm that I have read and understand the information sheet dated: **March 2008 (version 3)** for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my dental care or legal rights being affected.	☐
3	I understand that relevant sections of my dental notes and data collected during the study (information from the questionnaires and the video of my dental treatment appointment), may be looked at by individuals from [the University of Dundee and the University of St Andrews], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
4	I agree to the video record of my dental appointment to be held for analysis for a period of five years.	☐
5.	I understand that anonymised quotes from the video of my dental appointment may appear in publications.	☐
6	I agree to my GP being informed of my participation in the study.	☐
7	I agree to take part in the above study.	☐

Name of Patient *(Print name in capital letters)*	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

(1 for patient; 1 for researcher; 1 to be kept with dental notes)

Working with you to make Highland the healthy place to be

POSITIVE ABOUT DISABLED PEOPLE

Headquarters: Assynt House, Beechwood Park, INVERNESS IV2 3BW

Chair: Garry Coutts
Chief Executive: Dr Roger Gibbins BA MBA PhD
Highland NHS Board is the common name of Highland Health Board

Appendix 9

Modified Dental Anxiety Scale

(MDAS)

Questionnaire 1 (MDAS) Version 2 March 2008

NHS Highland

Can you tell us how anxious you get, if at all, with your dental visit?
Please tick the appropriate box.

1. If you went to your Dentist for TREATMENT TOMORROW, how would you feel?

Not Anxious ☐	Slightly Anxious ☐	Fairly Anxious ☐	Very Anxious ☐	Extremely Anxious ☐

2. If you were sitting in the WAITING ROOM (waiting for treatment), how would you feel?

Not Anxious ☐	Slightly Anxious ☐	Fairly Anxious ☐	Very Anxious ☐	Extremely Anxious ☐

3. If you were about to have a TOOTH DRILLED, how would you feel?

Not Anxious ☐	Slightly Anxious ☐	Fairly Anxious ☐	Very Anxious ☐	Extremely Anxious ☐

4. If you were about to have your TEETH SCALED AND POLISHED, how would you feel?

Not Anxious ☐	Slightly Anxious ☐	Fairly Anxious ☐	Very Anxious ☐	Extremely Anxious ☐

5. If you were about to have a LOCAL ANAESTHETIC INJECTION in your gum, above an upper back tooth, how would you feel?

Not Anxious ☐	Slightly Anxious ☐	Fairly Anxious ☐	Very Anxious ☐	Extremely Anxious ☐

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Appendix 10

Spielberger State Anxiety Inventory for State Anxiety

(STAI-S)

Questionnaire 2 (STAI-S) Version 1 March 2008

NHS Highland

A number of statements which people have used to describe themselves are given below.

Read each statement and then tick the appropriate box to the right of the statement to indicate how **you feel right now, that is, at this moment**. There are no right or wrong answers.

Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

		Not at all	Somewhat	Moderately so	Very much so
1.	I feel calm.....	☐	☐	☐	☐
2.	I am tense.....	☐	☐	☐	☐
3.	I feel upset.....	☐	☐	☐	☐
4.	I am relaxed.....	☐	☐	☐	☐
5.	I feel confident...	☐	☐	☐	☐
6.	I am worried.....	☐	☐	☐	☐